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Liberating Commercial Speech: Product Labeling Controls and the First Amendment


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LIBERATING COMMERCIAL SPEECH: PRODUCT LABELING CONTROLS AND THE FIRST AMENDMENT

*Lars Noah**
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No government agency has jurisdiction over the truth.

FBI Agent Fox Mulder, "The X-Files" (1994)

As federal regulators impose increasing limits on what manufacturers may say about their products, constitutional protections for commercial speech become ever more important. Indeed, the United States Supreme Court's most recent First Amendment decisions suggest meaningful regard for the value of advertising and labeling as types of protected expression. At the same time, however, federal lawmakers are imposing ever more onerous restrictions on promotional activities and product labeling.

On April 19, 1995, in *Rubin v. Coors Brewing Co.*,¹ the Supreme Court unanimously decided that a federal regulation prohibiting the disclosure of alcohol content in the labeling of malt beverages violated the First Amendment's protections for commercial speech. The Court's decision provides a useful vehicle for a discussion of consumer product labeling and advertising issues as they arise in a variety of different contexts. Fundamentally, the opinion suggests that the government may not deprive consumers of truthful information for their own protection.

Part I describes a number of federal regulatory limitations on the disclosure of truthful information to consumers. For example, the Food and Drug Administration (FDA) recently promulgated regulations which severely restrict the use of health claims and similar statements in food labeling. In addition, federal regulations currently prohibit the inclusion of certain truthful information to accompany government-mandated warning labels for a number of different product categories, and the FDA is drafting guidelines to limit the dissemination of accurate therapeutic information about prescription drugs and medical devices to physicians.

Part II provides a brief history of the Supreme Court's commercial free speech jurisprudence. Since initially extending the protections of the First Amendment to such speech twenty years ago, the Court has struggled to define the precise scope of these protections. The Court's unanimous decision in *Coors* represents an important extension and clarification of its prior holdings in this area.

Finally, Part III discusses the implications of the *Coors* decision for controversies surrounding federal efforts to control the dissemination of accurate information in pursuit of goals other than the protection of consumers from false or misleading promotional claims. Given its notable lack of deference to the judgments of federal policymakers, the

1. 115 S. Ct. 1585 (1995).

Court's recent decision may have an important impact on broadly applicable regulations such as the FDA's food labeling restrictions.

I. FEDERAL RESTRICTIONS ON PRODUCT LABELING

This Part introduces several federal limitations on the disclosure of truthful information related to consumer goods. The Coors litigation involved a challenge to longstanding prohibitions on the disclosure of alcohol content in the labeling and advertising of malt beverages. More recent examples involve primarily the FDA, an agency which regulates the labeling of a wide variety of consumer products.² FDA initiatives governing health claims in food labeling, warning statements across several product categories, and the exchange of scientific information about drugs and medical devices are described in turn. Each of these illustrations will be evaluated in Part III against the backdrop of the Supreme Court's commercial free speech decisions.

A. *Prohibitions on the Disclosure of Alcohol Content*

In 1935, shortly after the repeal of Prohibition by the Twenty-First Amendment,³ Congress enacted the Federal Alcohol Administration Act (FAAA).⁴ Among other things, the Act prohibited the disclosure of alcohol content in the labeling and advertising of malt beverages.⁵ At the time of enactment, Congress noted the difficulty of obtaining accurate measurements of alcohol content due to varying brewing conditions, so it sought to protect consumers from deception as well as ensure fair competition within the malt beverage industry.⁶ Because modern technology now enables brewers to measure the alcohol content

2. In a particularly controversial initiative, the FDA recently asserted authority over tobacco products and proposed significant restrictions on advertising purportedly aimed at teenage smokers. See 60 Fed. Reg. 41,314 (1995). The tobacco industry has already challenged these restrictions on First Amendment and other grounds. See Lars Noah & Barbara A. Noah, *Surrealism in the Proposed Regulation of Tobacco Products*, 48 ALA. L. REV. (forthcoming 1996); Claudia MacLachlan, *FDA Draws First in Tobacco Wars*, NAT'L L.J., Aug. 28, 1995, at A1, A21.

3. U.S. CONST. amend. XXI, § 1; see also Sidney J. Spaeth, Comment, *The Twenty-First Amendment and State Control Over Intoxicating Liquor: Accommodating the Federal Interest*, 79 CAL. L. REV. 161 (1991).

4. Federal Alcohol Administration Act, ch. 814, 49 Stat. 977 (1935) (codified as amended at 27 U.S.C. §§ 201-219a (1994)).

5. 27 U.S.C. § 205(e)(2), (f)(2) (1994).

6. See *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1547-48 (10th Cir. 1991) (quoting House Committee report and describing testimony about the difficulty in obtaining accurate alcohol content measurements in beer); see also *National Distrib. Co. v. United States Treasury Dep't*, 626 F.2d 997, 1004-12 (D.C. Cir. 1980) (detailing the FAAA's legislative history).

of their beverages very precisely,⁷ however, the original concern that consumers might be misled by inaccurate alcohol content labeling or advertising has largely disappeared.

The Treasury Department's Bureau of Alcohol, Tobacco, and Firearms (BATF) enforces the FAAA. In regulations implementing the statute, BATF prohibited the disclosure of alcohol content in the labeling and advertising of malt beverages,⁸ a class of products which includes beer.⁹ In addition, descriptive terms that suggest high alcohol content may not be used,¹⁰ but the regulations allow the use of terminology suggesting low alcohol content in certain circumstances.¹¹ By contrast, consistent with the requirements of the FAAA, the disclosure of alcohol content is permitted in the labeling of many wine products,¹² and it is required in the labeling of distilled liquors as well as wines containing more than fourteen percent alcohol.¹³

When Coors first challenged the prohibition against alcohol content labeling and advertising, the government emphasized its interest in preventing so-called "strength wars."¹⁴ The government argued that, if alcohol content disclosure were permitted, competing brewers would continually increase the alcohol content of their products in an effort to capture a larger share of the market. Although the asserted interest in preventing strength wars seems valid and substantial,¹⁵ the central issue

7. See, e.g., T.M. Dowhanick & I. Russell, *Advances in Detection and Identification Methods Applicable to the Brewing Industry*, in *BEER AND WINE PRODUCTION: ANALYSIS, CHARACTERIZATION, AND TECHNOLOGICAL ADVANCES* 13 (Barry H. Gump ed., 1993). Indeed, existing federal regulations assume that, within narrow tolerances, brewers can accurately measure alcohol content. See, e.g., 27 C.F.R. §§ 5.37(b), 7.26(b) (1993).

8. See 27 C.F.R. § 7.26(a) (1993) ("The alcohol's content and the percentage and quantity of the original extract shall not be stated unless required by State law."); *id.* § 7.54(c). BATF suspended § 7.26 in order to comply with the district court's order in *Coors* enjoining the enforcement of this regulation, and it promulgated an interim regulation permitting the disclosure of alcohol content on beer labels. See 58 Fed. Reg. 21,228, 21,232 (1993) (codified at 27 C.F.R. § 7.71 (1994)).

9. See 27 U.S.C. § 211(a)(7) (1994); 27 C.F.R. §§ 7.10, 7.24(d) (1993).

10. See 27 C.F.R. § 7.29(f) (1993) (prohibiting the use of words such as "strong," "extra strength," and "high test"); see also *id.* § 7.29(g) (prohibiting the use of numerals or other designs "which are likely to be considered as statements of alcoholic content").

11. See *id.* § 7.26(b).

12. See *id.* § 4.36(a) (requiring either content disclosure or type designation if the wine's alcohol content is 14% or less).

13. *Id.* §§ 4.36(a), 5.37(a). Distilled liquor labels may also include references to degrees of proof. *Id.* § 5.37(a)(2). Although separate statements of alcohol content generally may not appear in the advertising of wine products, see *id.* § 4.64(a)(8), alcohol content disclosure is mandatory in the advertising for distilled liquors, *id.* § 5.63(c).

14. See *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1548-49 (10th Cir. 1991).

15. The social and economic costs of increased alcohol consumption are undeniable. See,

addressed in the Coors litigation was whether the government legitimately can prevent beer manufacturers from including truthful, nonmisleading information about alcohol content in pursuit of such a broader social goal.¹⁶

B. *Limitations on Health Claims in Food Labeling*

In 1990, Congress enacted the Nutrition Labeling and Education Act (NLEA),¹⁷ a statute aimed at substantially reforming federal regulation of food product labeling to enable consumers to make more informed choices about their diets.¹⁸ Before that time, the FDA used a vague prohibition against "false or misleading" statements to regulate health messages in labeling.¹⁹ In addition to mandating the inclusion of comprehensive nutrition information in labeling, the NLEA prohibited all unapproved health claims,²⁰ and directed the FDA to approve health claims only when they were supported by "significant scientific agreement."²¹ The Act also delineated certain situations in which food companies would be barred from making even FDA-approved health claims.²²

e.g., J. Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270 JAMA 2207, 2208 (1993) ("Misuse of alcohol accounts for approximately 100,000 deaths each year, but the related health, social, and economic consequences of alcohol extend far beyond the mortality tables."); *Use of Alcohol Linked to Rise in Fetal Illness*, N.Y. TIMES, Apr. 7, 1995, at A27.

16. *See infra* Part II.C.

17. Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified in scattered sections of 21 U.S.C.).

18. *See* H.R. REP. NO. 538, 101st Cong., 2d Sess. 9-10 (1990) ("Health claims supported by a significant scientific agreement can reinforce the Surgeon General recommendations and help Americans to maintain a balanced and healthful diet."); 136 CONG. REC. S16,610 (1990) (statement of Sen. Hatch) ("Food companies should be able to advertise the health benefit of their product so long as these claims are not false or misleading."). A recent study of consumer use of the new nutrition label reveals, however, that Americans are not significantly altering their consumption habits. *See* Jennifer Steinhauer, *Food Labels Don't Change Eating Habits*, N.Y. TIMES, May 10, 1995, at B1.

19. *See* 21 U.S.C. § 343(a)(1) (1994). Under the FDA's 1973 nutrition labeling regulations, a food was deemed to be misbranded if its labeling claimed or implied "[t]hat the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom." 38 Fed. Reg. 2128 (1973) (codified as amended at 21 C.F.R. § 101.9(k)(1) (1993)). Although historically it had prohibited all health claims in the labeling of food products, the FDA temporarily liberalized its policy in the 1980s. *See* 55 Fed. Reg. 5176, 5184 (1990); 52 Fed. Reg. 28,843 (1987); *United States v. Undetermined Quantities of . . . "Exachol"*, 716 F. Supp. 787, 789-90 (S.D.N.Y. 1989).

20. 21 U.S.C. § 343(r)(1)(B) (1994).

21. *Id.* § 343(r)(3)(B)(i).

22. *See id.* § 343(r)(3)(A)(ii).

In 1993, the FDA published its final regulations implementing the NLEA.²³ Some of the most important aspects of these new food labeling rules include mandatory nutrition labeling,²⁴ guidelines for the use of nutrient content claims (such as "low fat"),²⁵ and restrictions on health messages in product labeling.²⁶ For instance, under the regulations as originally promulgated, a company could not have made the following truthful claim in the labeling of a food product containing folic acid:

The U.S. Centers for Disease Control (CDC) have encouraged all women of childbearing age to consume 0.4 milligrams of folic acid each day to reduce their risk of having a pregnancy which results in a neural tube birth defect such as spina bifida.²⁷

23. 58 Fed. Reg. 2066-2926 (1993) (codified as amended in scattered sections of 21 C.F.R. pt. 101); *see also* 59 Fed. Reg. 350-426 (1994) (codified as amended in scattered sections of 21 C.F.R. pt. 101) (dietary supplement labeling); 58 Fed. Reg. 632-85 (1993) (codified in scattered sections of 9 C.F.R. pts. 317, 381) (Department of Agriculture rules governing the labeling of meat and poultry food products). The FDA's initial "Regulatory Impact Analysis" includes the following observation: "If mostly incorrect claims are prohibited, consumers will benefit from only seeing those claims that are correct. On the other hand, if claims that are likely to be true are removed, this will decrease the total benefits of the 1990 amendments as consumers will lose valuable information." 56 Fed. Reg. 60,856, 60,869 (1991).

24. *See* 21 C.F.R. § 101.9 (1994).

25. *See id.* § 101.13. In addition to standardizing descriptors such as "high," "low" and "free" for different nutrients, these regulations flatly prohibit any references to nutrients or constituents such as "unsaturated fat," "omega-3 fatty acids" and "complex carbohydrates." *See* 58 Fed. Reg. 2079, 2090-91, 2100-01 (1993); *see also* 21 C.F.R. § 101.13(b) (1994) (prohibiting any express or implied content claims for nutrients which may not appear on the nutrition panel); 58 Fed. Reg. 2302, 2345 (1993) (explaining same).

26. *See* 21 C.F.R. § 101.14 (1994). Responding to the underutilization of health claims by food manufacturers, the FDA recently proposed several important revisions to these regulations. *See* 60 Fed. Reg. 66,206, 66,208 (1995).

27. *See* Centers for Disease Control, *Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects*, 41 MORB. & MORT. WKLY. REP. No. RR-14, 1 (1992). Notwithstanding this unqualified recommendation issued by one of its sister agencies in the Department of Health and Human Services, the FDA initially refused to authorize any health claim for folic acid. *See* 58 Fed. Reg. 2606, 2620 (1993). In response to heavy criticism, the FDA finally approved the claim a full year later, though only for dietary supplements and not conventional food products. *See* 59 Fed. Reg. 433, 434 (1994) (codified at 21 C.F.R. § 101.79 (1994)). Although recent studies suggest other important health protective effects of this micronutrient, *see A Little Folic Acid May Prove to Be Lifesaver*, GAINESVILLE SUN, July 25, 1995, at 1A, no truthful claims may be made in food labeling unless and until the FDA approves a petition requesting authorization of an appropriate health claim.

So far, the FDA has approved eight general claims relating nutrients to disease or other health-related conditions, and it has rejected five others.²⁸

The regulations set out in great detail how the levels of different nutrients may be characterized in product labeling. With regard to health claims, only those statements expressly approved by the Agency may be used. For instance, only if a product qualifies as "low fat," and only if it does not contain any disqualifying levels of certain components such as cholesterol or sodium,²⁹ may its labeling include a bland statement that a low fat diet "may" reduce the risk of "some cancers."³⁰ Moreover, such health claims could not appear on the labels of otherwise nutritionally worthless foods. For example, although it is undeniably true that jelly beans are "fat free," and therefore do not contribute a nutrient associated with some cancers, such a label statement would not be permitted under the FDA regulations.³¹

These strict labeling rules will also constrain food industry advertising. With the exception of prescription drugs and restricted medical devices, the FDA generally does not regulate product advertising.³² Instead, the Federal Trade Commission (FTC) exercises such authority.³³ The FDA's control over "labeling" is quite broad, however,

28. See 21 C.F.R. §§ 101.71-79 (1994). Examples of approved food-disease claims include calcium and osteoporosis, *id.* § 101.72; dietary lipids and cancer, *id.* § 101.73; sodium and hypertension, *id.* § 101.74; dietary saturated fat and cholesterol and risk of coronary heart disease, *id.* § 101.75; fiber-containing grain products, fruits, and vegetables and cancer, *id.* § 101.76; fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease, *id.* § 101.77; and fruits and vegetables and cancer, *id.* § 101.78. The Agency recently proposed approval of a health claim linking oat products and heart disease. See 61 Fed. Reg. 296 (1996). For a discussion of the scientific standard for approval of health claims under the NLEA, see Mara A. Michaels, Comment, *FDA Regulation of Health Claims Under the Nutrition Labeling and Education Act of 1990: A Proposal for a Less Restrictive Scientific Standard*, 44 EMORY L.J. 319 (1995).

29. 21 C.F.R. § 101.14(a)(5) (1994). Disqualifying nutrients foreclose health claims even if the claims relate to a disease condition (e.g., cancer) which is unaffected by the disqualifying nutrient (e.g., sodium). For example, the labeling of whole milk may not include the approved health claim regarding calcium and osteoporosis because the milk's high levels of saturated fat may increase the risk of heart disease. See 58 Fed. Reg. 2478, 2489 (1993).

30. 21 C.F.R. § 101.73(c) (1994). The regulation offers the following model health claim: "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers." *Id.* § 101.73(e)(1). The model claim for calcium and osteoporosis is even more cumbersome. See *id.* § 101.72(e).

31. See *id.* § 101.14(e)(6).

32. See 21 U.S.C. § 355(n), (q) (1994). The statute also calls for coordination between the FDA and the Federal Trade Commission (FTC) in the regulation of advertising for vitamin and mineral products. See *id.* § 378.

33. See 15 U.S.C. §§ 52-57 (1994).

reaching any written, printed, or graphic material that accompanies a product,³⁴ and the intended use of a product may be divined from advertising as well as labeling.³⁵ Thus, a great deal of promotional material is potentially subject to FDA controls. Moreover, the FTC often relies on FDA labeling restrictions when it determines whether advertising claims are false or deceptive.³⁶ Although it remains unclear whether the Commission will abide by the FDA's nutrient content claim and health message restrictions, it seems probable that the FTC will at least informally rely on these rules when deciding in particular cases whether advertising claims about a food product may be misleading.³⁷ In any event, the FDA's broad rulemaking efforts differ fundamentally from the FTC's case-by-case adjudicative approach,³⁸ a difference that may have some constitutional significance.³⁹

C. Restrictions on Product Warning Statements

The federal government imposes a wide variety of risk labeling requirements on the manufacturers of consumer products.⁴⁰ In addition to prescribing the precise language that must be used in labeling, agencies also restrict the use of warning statements in a number of

34. See 21 U.S.C. § 321(k), (m) (1994); *Kordel v. United States*, 335 U.S. 345, 348-50 (1948).

35. See 21 C.F.R. § 201.128 (1994); *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn.) (noting that it is "well established that the 'intended use' of a product, within the meaning of the [FD&C] Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source"), *aff'd*, 540 F.2d 947 (8th Cir. 1976).

36. See, e.g., *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1494-95 (1st Cir. 1989); *Thompson Medical Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 558-60 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985); *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 691 n.17 (3d Cir. 1982).

37. See F-D-C REPORTS ("The Tan Sheet"), May 16, 1994, at 27 (describing the FTC's new "enforcement policy statement" which allows properly qualified health claims in advertising for food products even if these claims are not approved by the FDA for use in labeling); see also Elisabeth A. Sachs, *Health Claims in the Marketplace: The Future of the FDA and the FTC's Regulatory Split*, 48 FOOD & DRUG L.J. 263 (1993); James M. Serafino, *Developing Standards for Health Claims—The FDA and the FTC*, 47 FOOD & DRUG L.J. 335 (1992).

38. See Richard S. Higgins & Fred S. McChesney, *Truth and Consequences: The Federal Trade Commission's Ad Substantiation Policy*, in PUBLIC CHOICE AND REGULATION: A VIEW FROM INSIDE THE FEDERAL TRADE COMMISSION 181, 182-84 (Robert J. Mackay et al. eds., 1987); Arthur Best, *Controlling False Advertising: A Comparative Study of Public Regulation, Industry Self-Policing, and Private Litigation*, 20 GA. L. REV. 1, 16-20 (1985); Peter Barton Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSM. L.J. 3, 9-20 (1986).

39. See *infra* Part III.A.5.

40. See Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 301-38 (1994).

circumstances. With regard to risk information generally, FDA regulations prohibit any "statement of differences of opinion with respect to warnings . . . required in labeling for food, drugs, devices, or cosmetics under the act."⁴¹ Thus, unless the FDA itself has prescribed cautionary statements that reflect the degree of uncertainty underlying a risk estimate, product manufacturers are prohibited from conveying such information because it may undermine the warnings mandated by the Agency.⁴²

In the labeling of nonprescription drug products (also referred to as over-the-counter (OTC) drugs), for instance, the FDA requires detailed warning statements with regard to all acute risks associated with these products. The Agency has promulgated regulations in the form of "monographs" which set out acceptable ingredient levels and combinations, along with the required labeling, for different product categories.⁴³ Manufacturers of OTC drug products may use only the precise warning language set out in the monographs or other applicable regulations.⁴⁴ Although manufacturers may choose to include other accurate cautionary information not prescribed by the FDA, this information must appear in some portion of the label other than the "Warnings" section.⁴⁵

41. 21 C.F.R. § 1.21(c)(1) (1994). Other agencies also prohibit the use of disclaimers to accompany warnings on the labels of consumer products. *See, e.g.*, 16 C.F.R. § 1500.122 (1994) (CPSC labeling requirements for hazardous substances); 40 C.F.R. § 156.10(a)(5)(viii) (1994) (EPA pesticide label warnings).

42. *See* 39 Fed. Reg. 33,229, 33,232 (1974) ("[T]here is no basis to permit warnings to be discounted by an opinion that the warning is really not necessary at all. . . . [A] warning must be unencumbered and unambiguous."). The FDA concluded that "where warnings are required, disclamatory opinions necessarily detract from the warning in such a manner as to be confusing and misleading." *Id.*; *see also* 40 Fed. Reg. 28,582, 28,583 (1975) ("[W]arnings about possible hazards associated with the use of a drug must, to be effective, remain undiluted by expressions of opinion discounting the risk.").

43. *See* 21 C.F.R. § 330.10(a) (1994). Examples of monograph product categories include night-time sleep aids, *id.* § 338.50(c); antacids, *id.* § 331.30(c); antihistamines, *id.* § 341.72(c); and anorectal drug products, *id.* § 346.50(c).

44. 21 C.F.R. § 330.1(c)(2)(iv) (1994); 51 Fed. Reg. 16,258, 16,263 (1986) ("The agency believes that concisely and consistently worded warnings are essential to the safe use of an OTC drug product and that permitting flexibility in this section of labeling could put consumers at risk."); 38 Fed. Reg. 31,260, 31,264 (1973); *see also* Stephen H. McNamara, *FDA Regulation of Labeling and the Developing Law of Commercial Free Speech*, 37 FOOD DRUG COSM. L.J. 394, 400 (1982) (criticizing this policy). The FDA recently gave manufacturers some limited choice in formulating OTC warning statements, permitting the interchange of words such as "consult" and "ask," and "physician" and "doctor." 59 Fed. Reg. 3998, 4000 (1994) (codified at 21 C.F.R. § 330.1(i) (1994)).

45. *See* 56 Fed. Reg. 63,554, 63,566 (1991) (discussing warning that cautioned against using OTC dandruff products on children under two years of age, a warning recommended by an expert panel but rejected as unnecessary by the FDA); 50 Fed. Reg. 2124, 2128 (1985) (even

D. *Restraints on Continuing Medical Education Programs*

In November 1992, the FDA published what it characterized as a "Draft Policy Statement" to address industry-supported scientific and educational activities concerning drugs and medical devices.⁴⁶ This document cautions that continuing medical education (CME) programs and scientific symposia funded by the pharmaceutical and medical device industries will be subject to regulation as promotional labeling or advertising for any products discussed during these programs except in limited circumstances where sponsoring companies ensure that the program will be independent and objective.⁴⁷ FDA officials have repeatedly suggested that many industry-sponsored CME events are merely elaborate advertising opportunities and that the scientific information presented tends to be self-serving or even inaccurate.⁴⁸

By enumerating several steps for ensuring independence in program content, the *Draft Policy Statement* purports to strike "a proper balance between the need for industry-supported dissemination of current scientific information and the need to ensure that industry advertising activities meet the requirements of the law."⁴⁹ Although characterized as defining a safe harbor, the *Draft Policy Statement* represents a significant extension of the FDA's traditional controls over the labeling and advertising of prescription drugs and medical devices, potentially limiting the robust exchange of scientific information about important therapeutic advances.⁵⁰ A further analysis of these and other federal

truthful and nonmisleading information "may not appear in any portion of the labeling required by the monograph and may not detract from such required information").

46. 57 Fed. Reg. 56,412 (1992). In the wake of strong industry reaction to the *Draft Policy Statement*, the FDA extended the comment deadline. 58 Fed. Reg. 6126 (1993). To date, no final rule or guideline has been issued. In response to a recent citizen petition requesting the withdrawal of the *Draft Policy Statement*, however, the Agency invited additional comments. See 59 Fed. Reg. 59,820 (1994).

47. See 57 Fed. Reg. at 56,412-13.

48. See, e.g., *id.* at 56,412; David A. Kessler & Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising and Promotion*, 264 JAMA 2409, 2412 (1990). For a response to some of these arguments, see Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 FOOD & DRUG L.J. 309, 322-32 (1992).

49. 57 Fed. Reg. at 56,412; see also David G. Adams, *FDA Policy on Industry-Supported Scientific and Educational Activities: Current Developments*, 47 FOOD & DRUG L.J. 629 (1992); cf. 21 U.S.C. § 343-2 (1994) (excluding from the definition of "labeling" certain scientific publications when distributed by manufacturers or retailers of dietary supplements).

50. See Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PROD. & TOXICS LIAB. 139, 142-46 & n.34 (1994). Congress is considering proposals which would allow manufacturers to distribute peer-reviewed scientific literature concerning off-label uses. See Elyse Tanouye, *Drug Makers Seek Relaxed Restrictions on Marketing*, WALL ST. J.,

restrictions on the dissemination of truthful information must be deferred, however, until after a discussion of the protections afforded commercial speech under the First Amendment.

II. COMMERCIAL SPEECH AND THE FIRST AMENDMENT

Until recently, the United States Supreme Court had not directly addressed the scope of First Amendment protections for product labeling. Most of the earlier cases dealt with advertising of goods and services. Even so, it seemed reasonable to conclude that information appearing on the label of a product deserved at least as much protection as promotional claims made in other media. This Part discusses the evolution of the commercial speech doctrine and examines how the decision in *Coors* helps explicate the relevant constitutional framework.

A. Rationales for Protecting Commercial Speech

Since the mid-1970s, the Supreme Court has recognized that advertising enjoys some of the First Amendment's guarantees for freedom of expression. In the first commercial speech case in this line, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*,⁵¹ the Court struck down a state prohibition against the advertising of prescription drug prices. The question in that case was "whether speech which does no more than propose a commercial transaction is so removed from any exposition of ideas, and from truth, science, morality, and arts . . . that it lacks all protection."⁵² The Court decided that even such purely commercial speech, bereft of all the other qualities typically associated with protected speech, still deserved some constitutional protection, noting that the public's interest in the free flow of commercial information might be "as keen, if not keener by far" than its interest in political debate.⁵³

Aug. 31, 1995, at B1; *see also* 60 Fed. Reg. 62,471, 62,472 (1995) (inviting comments on draft FDA guidance which would allow companies to disseminate reprints of peer-reviewed scientific articles).

51. 425 U.S. 748 (1976); *see also* *Bigelow v. Virginia*, 421 U.S. 809, 826 (1975) (noting that the "relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas"). Prior to this time, the Court had suggested that the First Amendment placed no limitations on government regulation of commercial advertising. *See* *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942); *see also* Alex Kozinski & Stuart Banner, *The Anti-History and Pre-History of Commercial Speech*, 71 TEX. L. REV. 747, 754-74 (1993).

52. *Virginia State Bd.*, 425 U.S. at 762 (citations and internal quotation marks omitted).

53. *Id.* at 763. The Court added that the information at issue could have a profound impact on the consumer's quality of life: "When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-64.

In its subsequent decisions, the Supreme Court repeatedly has recognized the value of advertising as one mechanism for the dissemination of information.⁵⁴ After all, promotional advertising involves the dissemination of information about a product which the seller "presumably knows more about than anyone else."⁵⁵ One year after *Virginia State Board*, in striking down a blanket prohibition on attorney price advertising in newspapers, Justice Blackmun wrote that:

[S]ignificant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. And commercial speech serves to inform the public of the availability, nature, and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system.⁵⁶

In *Bolger v. Youngs Drug Products Corp.*,⁵⁷ for example, the Court held that a federal law prohibiting unsolicited mailings was unconstitutional when applied to a pharmaceutical company distributing informational pamphlets which encouraged the use of contraceptives. The Court recognized that such materials—containing information related to public health matters—deserved a high degree of protection under the Constitution.⁵⁸

54. See, e.g., *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).

Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information. . . . Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all. . . . The First Amendment's concern for commercial speech is based on the informational function of advertising.

Id. at 561-63. For the claim that most advertising is devoid of informational content, see Ronald K.L. Collins & David M. Skover, *Commerce & Communication*, 71 TEX. L. REV. 697, 710-27 (1993). But see Rodney A. Smolla, *Information, Imagery, and the First Amendment: A Case for Expansive Protection of Commercial Speech*, 71 TEX. L. REV. 777, 794-800 (1993) (challenging the accuracy of this descriptive thesis).

55. *Virginia State Bd.*, 425 U.S. at 772 n.24; see also Burt Neuborne, *The First Amendment and Government Regulation of Capital Markets*, 55 BROOK. L. REV. 5, 31-32 (1989).

56. *Bates v. State Bar*, 433 U.S. 350, 364 (1977) (citations omitted).

57. 463 U.S. 60 (1983).

58. See *id.* at 69 ("[W]here . . . a speaker desires to convey truthful information relevant to important social issues such as family planning and the prevention of venereal disease, we have previously found the First Amendment interest served by such speech paramount.").

Since *Virginia State Board*, the Court has continued to develop and refine its definition of commercial speech, though it has had difficulty assessing restrictions on speech which contains both commercial and noncommercial elements.⁵⁹ Traditionally safeguarded speech enjoys full protection notwithstanding the fact that it may pertain to a commercial activity; the mere existence of some underlying profit motive does not trigger a lesser degree of constitutional scrutiny.⁶⁰

The type of commercial speech accorded somewhat lesser constitutional protection represents only a narrow category, namely "expression related solely to the economic interests of the speaker and its audience."⁶¹ In *Virginia State Board*, the Court recognized that the "durability" and "hardiness" of commercial speech reduces the risk that it might be chilled by regulation.⁶² These attributes of commercial speech, together with the fact that disseminators of such expression are better able to determine its truthfulness, may "make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive."⁶³

Thus, because of its greater durability, commercial speech may be regulated in order to prevent consumer deception. Ever since *Virginia*

59. See Alan Howard, *The Constitutionality of Deceptive Speech Regulations: Replacing the Commercial Speech Doctrine with a Tort-Based Relational Framework*, 41 CASE W. RES. L. REV. 1093 (1991); David F. McGowan, Comment, *A Critical Analysis of Commercial Speech*, 78 CAL. L. REV. 359, 371-81 (1990).

60. Board of Trustees of the State Univ. v. Fox, 492 U.S. 469, 482 (1989) ("Some of our most valued forms of fully protected speech are uttered for a profit.").

61. *Central Hudson*, 447 U.S. at 561; see also *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) ("To require a parity of constitutional protection for commercial and noncommercial speech alike could invite dilution, simply by a leveling process, of the force of the Amendment's guarantee with respect to the latter kind of speech. Rather than subject the First Amendment to such a devitalization, we instead have afforded commercial speech a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values.").

62. *Virginia State Bd.*, 425 U.S. at 772 n.24. But cf. McGowan, *supra* note 59, at 444-48 (arguing that full First Amendment protection for commercial speech would not undermine the government's ability to control false advertising).

63. *Virginia State Bd.*, 425 U.S. at 772 n.24; see also *Meese v. Keene*, 481 U.S. 465, 482 (1987) (noting that it would be impermissibly "paternalistic" to strike down disclosure requirements because "a zeal to protect the public from 'too much information' could not withstand First Amendment scrutiny"); cf. Daniel A. Farber, *Commercial Speech and First Amendment Theory*, 74 NW. U. L. REV. 372, 385-86 (1979) (questioning the distinction between commercial and political speech based on the relative ease of verification); Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 634-52 (1990) (disputing grounds for distinguishing commercial speech); McGowan, *supra* note 59, at 405-10 (same).

State Board, however, the Court has treated with suspicion government efforts to achieve collateral goals through the suppression of truthful and nonmisleading information.⁶⁴

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented.⁶⁵

Commercial speech is not protected under the First Amendment solely or even primarily for the benefit of the speaker but rather serves the interests of listeners. Although the government may protect consumers from false or misleading product claims, it generally may not prohibit truthful and nondeceptive claims in pursuit of some other end.

B. *Elaboration of the Central Hudson Test*

In 1980, in *Central Hudson Gas & Electric Corp. v. Public Service Commission*,⁶⁶ the Court addressed a state regulation of commercial speech whose goal was to influence consumer behavior rather than protect the public from potentially misleading information. It announced a four-part test for evaluating commercial free speech claims:

At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest

64. See, e.g., *Central Hudson*, 447 U.S. at 566 n.9 ("We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy."); *Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85, 96-97 (1977) (striking down prohibition on the posting of "For Sale" signs in an effort to reduce the departure of white homeowners from racially integrating neighborhoods); *Virginia State Bd.*, 425 U.S. at 769-70 ("[T]he State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance. . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.").

65. *Edenfield v. Fane*, 113 S. Ct. 1792, 1798 (1993).

66. 447 U.S. 557 (1980).

asserted, and whether it is not more extensive than is necessary to serve that interest.⁶⁷

In other words, assuming that the speech does not relate to some unlawful activity and is not inherently misleading, the government may restrict commercial speech only to achieve a substantial interest, and then only to the extent necessary.

The issue in *Central Hudson* was whether utility company advertisements promoting the consumption of electricity could be prohibited by the State of New York's Public Service Commission without running afoul of the First Amendment. Applying the first prong of its newly elaborated test, the Court found that the advertising related to a lawful activity and was not misleading.⁶⁸ Under the second prong, the government's asserted interests in encouraging energy conservation and promoting fair utility rates were deemed to be substantial.⁶⁹ Under the third prong of its test, however, the Court noted that the link between the advertising prohibition and the utility's rate structure was tenuous, even if there was an "immediate connection" between the advertising at issue and demand for electricity.⁷⁰ Finally, the Court determined that the Commission's order failed the fourth prong of the test because it was "more extensive than necessary" to accomplish the government's goals.⁷¹ The Commission failed to show that a more limited approach

67. *Id.* at 566. It should be noted, however, that in a number of the Court's most recent decisions, the four-part *Central Hudson* analysis has evolved somewhat: the initial prong became a threshold inquiry and the other prongs now constitute a tripartite test. *See, e.g., Edenfield*, 113 S. Ct. at 1798. This difference does not appear to have had any substantive effect on the decisions, though it may suggest that the first prong has atrophied into a mere formality while emphasizing that the more relevant prongs parallel the intermediate scrutiny test used in other constitutional contexts. Evidently only three cases, all predating *Central Hudson*, were resolved at the threshold. *See Friedman v. Rogers*, 440 U.S. 1, 12-13 (1979) (rejecting challenge to state prohibition on the use of trade names by optometrists: "Because these ill-defined associations of trade names with price and quality information can be manipulated by the users of trade names, there is a significant possibility that trade names will be used to mislead the public."); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 468 (1978) (upholding prohibition on in-person attorney solicitation); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 388 (1973) ("We have no doubt that a newspaper constitutionally could be forbidden to publish a want ad proposing a sale of narcotics or soliciting prostitutes.").

68. *Central Hudson*, 447 U.S. at 566.

69. *Id.* at 569.

70. *Id.* ("[T]he Commission's laudable concern over the equity and efficiency of appellant's rates does not provide a constitutionally adequate reason for restricting protected speech.").

71. *Id.* at 569-70.

to regulating advertising, something short of an outright prohibition, could not accomplish its legitimate ends.⁷²

In the years following the *Central Hudson* decision, it became apparent that the four-prong test was ambiguous and difficult to apply.⁷³ To some extent, of course, the questions posed by the test are not entirely distinct from one another. Moreover, even if the four parts are carefully differentiated, the Court's application of any particular prong has proven to be quite unpredictable. Both before and after *Central Hudson*, controls on lawyer advertising have been the most frequent subject of commercial free speech review.⁷⁴ In one such case, the Court reviewed a rule which prohibited attorneys from, among other things, including in their advertisements any information outside of that specified in ten limited categories.⁷⁵ The Court concluded that there was no substantial state interest to justify the restrictions, and that there was nothing inherently misleading about the type of advertisement in question, despite the fact that it deviated from the prescribed format.⁷⁶ Moreover, the Court noted that the absolute prohibitions set forth in the rule were not the only alternatives which would effectively accomplish the state's asserted goal of preventing consumer deception.⁷⁷

By contrast, in *Zauderer v. Office of Disciplinary Counsel*,⁷⁸ the Court upheld a state professional responsibility rule prohibiting deceptive advertising.⁷⁹ The rule required the disclosure of attorneys' fee information in print advertisements. In applying *Central Hudson's*

72. See *id.*; see also *id.* at 565 ("The State cannot . . . completely suppress information when narrower restrictions on expression would serve its interests as well.").

73. See Kozinski & Banner, *supra* note 63, at 631; Mary B. Nutt, Recent Development, *Trends in First Amendment Protection of Commercial Speech*, 41 VAND. L. REV. 173, 189-205 (1988).

74. See, e.g., *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91 (1990) (plurality); *Shapiro v. Kentucky Bar Ass'n*, 486 U.S. 466 (1988); *Bates v. State Bar*, 433 U.S. 350 (1977); see also Sandra L. DeGraw & Bruce W. Burton, *Lawyer Discipline and "Disclosure Advertising": Towards a New Ethos*, 72 N.C. L. REV. 351 (1994); Geoffrey C. Hazard, Jr. et al., *Why Lawyers Should Be Allowed to Advertise: A Market Analysis of Legal Services*, 58 N.Y.U. L. REV. 1084 (1983).

75. *In re R.M.J.*, 455 U.S. 191, 194-96 (1982). For example, attorneys were prohibited from listing the tribunals before which they were admitted to practice. See *id.* at 198.

76. See *id.* at 205-07.

77. *Id.* at 206.

78. 471 U.S. 626 (1985).

79. See *id.* at 650-53, 655-56. The Court also found that it was improper to reprimand the attorney in question for his use of a non-deceptive illustration and his offer of attorney services regarding a specific legal problem in a print advertisement. See *id.* at 641-49. Both rules banning these practices were held unconstitutional under a *Central Hudson* analysis.

fourth prong, the Court demanded only that the state regulation be "reasonably related" to the asserted governmental interest.⁸⁰

We reject appellant's contention that we should subject disclosure requirements to a strict "least restrictive means" analysis under which they must be struck down if there are other means by which the State's purposes may be served. Although we have subjected outright prohibitions on speech to such analysis, all our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech.⁸¹

The Court feared that the average consumer of legal services, when reading an advertisement about a contingency fee arrangement stating that no "fees" would be incurred unless the suit was successful, would not understand that court "costs" might still be incurred.⁸²

During the late 1980s, the Court appeared to embrace an even weaker interpretation of the nexus prongs of *Central Hudson*, thereby significantly diluting the protections accorded commercial speech. In *Posadas de Puerto Rico Associates v. Tourism Co.*,⁸³ for example, it reviewed a statute which prohibited casino advertising directed at residents of Puerto Rico but permitted such advertising when aimed at non-residents. Initially, the Court noted that casino gambling was lawful in Puerto Rico, that the advertising in question was not misleading, and that the government had a substantial interest in protecting the welfare of its citizens.⁸⁴ In applying the nexus requirements of the *Central Hudson* analysis, the Court showed significant deference to the Puerto Rican legislature's conclusion that the advertising ban would discourage gambling among residents, stating that the legislature's choice was a "reasonable one."⁸⁵ Under the fourth prong, the Court simply stated

80. *Id.* at 651.

81. *Id.* at 651-52 n.14.

82. *See id.* at 652-53.

83. 478 U.S. 328 (1986).

84. *See id.* at 340-41.

85. *See id.* at 342. *Posadas* attracted a great deal of academic criticism. *See, e.g.*, Donald E. Lively, *The Supreme Court and Commercial Speech: New Words with an Old Message*, 72 MINN. L. REV. 289, 299-304 (1987); Ronald D. Rotunda, *The Constitutional Future of the Bill of Rights: A Closer Look at Commercial Speech and State Aid to Religiously Affiliated Schools*, 65 N.C. L. REV. 917, 923-29 (1987); Frederick Schauer, *Commercial Speech and the Architecture of the First Amendment*, 56 U. CIN. L. REV. 1181, 1182 & n.1 (1988) (characterizing *Posadas* as irreconcilable with *Central Hudson*). *But see* Daniel H. Lowenstein, "Too Much Puff": *Persuasion, Paternalism, and Commercial Speech*, 56 U. CIN. L. REV. 1205, 1230-31

that the ban was no more extensive than necessary to accomplish its goal because it applied only to Puerto Rican residents,⁸⁶ adding that it was the state's prerogative to decide whether an alternative approach (such as requiring warnings against gambling) might be as effective.⁸⁷

The Supreme Court's decisions from the last few years suggest, however, substantially greater protection for commercial speech. In *City of Cincinnati v. Discovery Network, Inc.*,⁸⁸ for example, it considered the constitutionality of a municipal ordinance prohibiting the distribution of commercial handbills from newsracks on public property.⁸⁹ The Court held that the City had failed to demonstrate a "reasonable fit," as required under the latter two steps of the *Central Hudson* test, between its asserted interests in safety and esthetics and its prohibition on newsracks for free commercial magazines but not for newspapers.⁹⁰ The Court declared the ordinance unconstitutional partly because the original rationale for its passage was no longer cogent.⁹¹

Similarly, in *Edenfield v. Fane*,⁹² the majority found that the State of Florida had failed to demonstrate a reasonable fit between its broad prophylactic rule against personal solicitation of clients by certified

(1988) (arguing that *Posadas* was consistent with the Court's differing treatment of informational and non-informational advertising).

86. *Posadas*, 478 U.S. at 343; see also *Board of Trustees of the State Univ. v. Fox*, 492 U.S. 469, 475-77 (1989) (upholding rule barring representatives of all but a few types of businesses from operating on state university campuses because the government had a substantial interest in promoting a safe, secure educational atmosphere and preventing exploitation of students by commercial enterprises). After passing over the third prong of the test in a relatively cursory fashion, the Court in *Fox* proceeded to analyze the rule in detail under the fourth prong, reiterating that it "requires something short of a least-restrictive-means standard." *Id.* at 476-77; see also Albert P. Mauro, Jr., Comment, *Commercial Speech After Posadas and Fox: A Rational Basis Wolf in Intermediate Sheep's Clothing*, 66 TUL. L. REV. 1931, 1950 (1992) ("Taken together, *Posadas* and *Fox* represent a substantial reduction in the protection afforded commercial speech.").

87. See *Posadas*, 478 U.S. at 344 ("The legislature could conclude, as it apparently did here, that residents of Puerto Rico are already aware of the risks of casino gambling, yet would nevertheless be induced by widespread advertising to engage in such potentially harmful conduct."); see also *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (plurality) ("hesitat[ing] to disagree with the accumulated, commonsense judgments of local lawmakers").

88. 113 S. Ct. 1505 (1993).

89. See *id.* at 1508.

90. See *id.* at 1510.

91. The Court explained that the ordinance "was an outdated prohibition against the distribution of any commercial handbills on public property. It was enacted long before any concern about newsracks developed. Its apparent purpose was to prevent the kind of visual blight caused by littering, rather than any harm associated with permanent, freestanding dispensing devices." *Id.* (adding that the City's action would have eliminated only 62 out of almost 2,000 newsracks).

92. 113 S. Ct. 1792 (1993).

public accountants and its conceded interests in ensuring that such communications were not false, misleading, or coercive. The Court appeared to strengthen prong three of the *Central Hudson* analysis, holding that the challenged regulation must advance the government interest "in a direct and material way."⁹³ According to the Court in *Edenfield*, the state "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."⁹⁴ The Court declined to accept the state's assertion that in-person solicitation was obviously harmful and instead required the State to supply evidence to bolster its claim.⁹⁵

In *United States v. Edge Broadcasting Co.*,⁹⁶ by contrast, the Court showed significant deference in evaluating the constitutionality of a 1934 federal statute prohibiting the broadcasting of lottery advertising on radio and television stations. The statutory prohibition applied only to stations licensed in those states which did not sponsor lotteries.⁹⁷ After assuming that the advertising was not misleading, and noting that Congress' goal of protecting the interests of nonlottery states was substantial,⁹⁸ the Court turned to the nexus elements of the *Central Hudson* analysis. Under prong three, it found that the ban directly advanced the government's interest in accommodating conflicting state lottery policies.⁹⁹ Applying prong four in a similarly cursory fashion,

93. *Id.* at 1798.

94. *Id.* at 1800; *see also* *Ibanez v. Florida Dep't of Business & Professional Regulation*, 114 S. Ct. 2084, 2086-91 (1994) (overturning a Board of Accountancy order censuring one of its members for including references in her law office letterhead and advertising to her licenses as a certified public accountant (CPA) and certified financial planner (CFP)). In *Ibanez*, the Court found that there was no specific evidence that the use of the CPA designation in advertising was misleading, and it also emphasized that the state had failed to present any evidence that anyone had been misled by Ibanez's truthful representation of her CPA credential. *Id.* at 2089 ("[A]s long as Ibanez holds an active CPA license from the Board we cannot imagine how consumers can be misled by her truthful representation to that effect."); *see also id.* at 2090 (finding that the CFP designation was truthful and not misleading, and concluding that the Board had failed to satisfy its burden to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree" (internal quotation marks omitted)).

95. *See Edenfield*, 113 S. Ct. at 1800-01; *see also* *FCC v. Beach Communications*, 113 S. Ct. 2096, 2102 (1993) (explaining that only on minimum rationality review may a legislative choice "be based on rational speculation unsupported by evidence or empirical data").

96. 113 S. Ct. 2696 (1993).

97. *See id.* at 2701.

98. *See id.* at 2703. The relatively greater attention to the second prong of the *Central Hudson* analysis in this case, which entailed a more precise definition of the governmental interest underlying the statute, suggests that the Court will focus on different prongs of the *Central Hudson* test in different situations.

99. *See id.* at 2704. Strangely, in discussing how the statute directly advanced the asserted

the Court concluded that the ban was reasonable under the intermediate scrutiny standard.¹⁰⁰

Over the fifteen years since it announced the *Central Hudson* test, the United States Supreme Court has become increasingly critical of state and local restrictions on commercial speech, though *Edge Broadcasting* suggested greater deference in its review of federal statutes.¹⁰¹ Taken together, the Court's decisions demonstrate that the judiciary will continue to scrutinize assertions that a challenged restriction actually advances a substantial government interest, typically (but not exclusively) an interest in preventing false, misleading, or coercive commercial speech. To be sure, the Justices did not speak unanimously in rendering these decisions, and the divergent outcomes may be somewhat difficult to reconcile, but the bottom line is a continued recognition of the value of commercial speech.

C. *The Supreme Court's Resolution of the Coors Litigation*

In one of its latest commercial free speech decisions, *Rubin v. Coors Brewing Co.*,¹⁰² the Court provided important insights about this still relatively young First Amendment doctrine. In 1987, the Adolph Coors Company petitioned BATF for permission to include the alcohol content, in terms of a numerical percentage, on the labels of its beer

governmental goals, the Court cited examples of other possible statutory schemes which would have had a more overinclusive effect (such as banning all lottery advertising nationwide, or forbidding stations in lottery states from carrying lottery advertisements if their signals reached neighboring nonlottery states). *See id.* This type of argument ordinarily is considered under the fourth prong of the *Central Hudson* analysis.

100. *See id.* at 2705. In determining that the statute was no more extensive than necessary to achieve the governmental interest, the Court discussed the application of the restriction to *Edge Broadcasting*, concluding that "applying the restriction to a broadcaster such as *Edge* directly advances the governmental interest in enforcing the restriction in nonlottery States, while not interfering with the policy of lottery States." *Id.*

101. *Id.* at 2704. This special deference accorded to congressional factfinding has parallels in the Court's previous Equal Protection jurisprudence. *See Metro Broadcasting, Inc. v. FCC*, 497 U.S. 547, 565 (1990) ("[R]ace-conscious classifications adopted by Congress to address racial and ethnic discrimination are subject to a different standard than such classifications prescribed by state and local governments."); *Fullilove v. Klutznick*, 448 U.S. 448, 472 (1980) (Burger, C.J., concurring) (noting that the Court is "bound to approach [its] task with appropriate deference to the Congress, a co-equal branch"); *cf. Richmond v. J.A. Croson Co.*, 488 U.S. 469, 491-92 (1989) (showing less deference in reviewing municipal ordinance). In a 1995 decision, however, the Court overturned *Metro Broadcasting*, holding that even federally-mandated programs that use race-based classifications are subject to strict scrutiny and must be narrowly-tailored to meet a compelling governmental objective. *See Adarand Constructors, Inc. v. Peña*, 115 S. Ct. 2097, 2113-14 (1995).

102. 115 S. Ct. 1585 (1995).

products, but the Bureau denied the petition.¹⁰³ As previously explained, the FAAA prohibits the disclosure of alcohol content in the labeling of malt beverages unless otherwise required by state law.¹⁰⁴

Coors responded by filing a complaint in federal district court against BATF and the Secretary of the Treasury, claiming that its proposed labeling and advertising were protected under the First Amendment. Department of Justice lawyers representing the defendants conceded that the challenged restrictions were unconstitutional,¹⁰⁵ but the United States House of Representatives intervened to defend the statute, arguing that the prohibition was necessary to further a substantial governmental interest in preventing strength wars among brewers of malt beverages.¹⁰⁶ The district court held that the statute violated the First Amendment and enjoined BATF from enforcing the relevant provisions of the statute and implementing regulations against Coors.¹⁰⁷

On appeal, the United States Court of Appeals for the Tenth Circuit agreed that Coors' proposed alcohol content labeling was protected commercial speech but added that the asserted government interest was substantial.¹⁰⁸ Because it found genuine issues of material fact concerning the question of whether the regulation directly advanced the government's interests, the Tenth Circuit remanded the case to the district court for further proceedings.¹⁰⁹ After the district court again held for Coors, the Tenth Circuit affirmed, concluding that BATF's regulation did not advance the government's interests in a direct and material way because the government had failed to show any relationship between alcohol content disclosure in labeling and strength

103. See Letter from Bruce L. Weininger, Chief, Industry Compliance Div., BATF, to Adolph Coors Co. (May 4, 1987), reprinted in Petition for Certiorari at 73a, *Coors* (No. 93-1631).

104. 27 U.S.C. § 205(e)(2) (1994). The FAAA also prohibits the disclosure of alcohol content in advertising. See *id.* § 205(f)(2). Initially, the district court decided that both the labeling and advertising restrictions were unconstitutional. See *Adolph Coors Co. v. Baker*, Civ. No. 87-Z-977 (D. Colo. May 31, 1989), reprinted in Petition for Certiorari at 43a, *Coors* (No. 93-1631). After remand, however, Coors apparently did not pursue its challenge to the advertising prohibition, and the district court only held the labeling prohibition to be unconstitutional. See *Adolph Coors Co. v. Baker*, 1992 U.S. Dist. LEXIS 18156, at *17 (D. Colo. Oct. 29, 1992), *aff'd*, *Adolph Coors Co. v. Bentsen*, 2 F.3d 355 (10th Cir. 1993), *aff'd*, 115 S. Ct. 1585 (1995). The implicitly rejected challenge to the advertising prohibition was never pressed on appeal. See *Coors*, 115 S. Ct. at 1588.

105. See *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991) (describing district court's unpublished decision).

106. See *id.*

107. See *id.*

108. See *id.* at 1547-49.

109. *Id.* at 1554.

wars.¹¹⁰ Indeed, the court speculated that most consumers would use alcohol content information to select beer with lower rather than higher alcohol content.¹¹¹

Thereupon, the Supreme Court granted the government's petition for certiorari.¹¹² In a unanimous decision, the Court affirmed the Tenth Circuit's judgment.¹¹³ From the outset of the litigation, the government admitted that the proposed alcohol content disclosure related to a lawful activity and was not misleading.¹¹⁴ Before the Court, the government asserted two main interests to justify its labeling ban. First, it reiterated the claim that the statute prevents brewers from engaging in strength wars.¹¹⁵ Second, and apparently for the first time in the course of the litigation, the government argued that the prohibition facilitates state regulation of alcoholic beverages.¹¹⁶ Regarding this latter claim, the Court concluded that states already enjoy adequate authority to ban the disclosure of alcohol content and that, therefore, the federal government lacks any substantial interest in preserving the states' authority.¹¹⁷ The

110. *Adolph Coors Co. v. Bentsen*, 2 F.3d 355, 358-59 (10th Cir. 1993), *aff'd*, 115 S. Ct. 1585 (1995).

111. *Id.* at 359 (noting that "the vast majority of consumers . . . value taste and lower calories—both of which are adversely affected by increased alcohol strength"). It should be remembered, however, that BATF permitted brewers to make "low" or "reduced" alcohol content claims in the labeling of their products. *See* 27 C.F.R. § 7.26(b) (1993).

112. 114 S. Ct. 2671 (1994). The numerous amicus briefs filed on both sides of the issue attest to the interest generated by this case. Briefs in support of Coors were filed by the Association of National Advertisers and Public Citizen, among others. Briefs in support of the government were filed by the National Governors' Association and the Center for Science in the Public Interest, among others.

113. *See Rubin v. Coors Brewing Co.*, 115 S. Ct. 1585, 1594 (1995). Only Justice Stevens wrote separately. *Id.* at 1594-97 (Stevens, J., concurring in judgment) (arguing that alcohol content disclosure restrictions should be evaluated under the test for pure rather than commercial speech).

114. *Id.* at 1590. Even so, one amicus made the argument that alcohol content disclosure is inherently misleading. *See Brief of Amicus Curiae Submitted by the Center for Science in the Public Interest in Support of Petitioners at 5, Coors* (No. 93-1631) ("While technically true, such labeling would deceptively make beer appear to be less intoxicating than wine and liquor when in fact beer is not" because of its larger average serving size.).

115. *See Coors*, 115 S. Ct. at 1590. Although the significance of this interest in the abstract went largely uncontested, Coors argued that the fear of strength wars was not in fact the true rationale underlying the governmental policy. *See id.*

116. *Id.* at 1591 (analogizing to *United States v. Edge Broadcasting Co.*, 113 S. Ct. 2696 (1993)).

117. *Id.* ("Even if the Federal Government possessed the broad authority to facilitate state powers, in this case the Government has offered nothing that suggests that States are in need of federal assistance. States clearly possess ample authority to ban the disclosure of alcohol content—subject, of course, to the same First Amendment restrictions that apply to the Federal Government.").

Court agreed, however, that the government's interest in preventing strength wars was substantial and proceeded to apply the nexus components of the *Central Hudson* test to the labeling restriction.

The Court characterized the last two steps in the *Central Hudson* test as involving "a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends."¹¹⁸ After an examination of the FAAA's regulatory scheme, the Court concluded that the government's approach was irrational.¹¹⁹ For example, the statute prohibits alcohol content labeling on beers, but permits it on some wines, and affirmatively requires it on distilled liquors and other wines.¹²⁰ The Court also noted an inconsistency in the treatment of labeling and advertising. Alcohol content may not be disclosed in labeling unless required by state law, but statements of alcohol content in advertising are prohibited only in States which affirmatively forbid such statements.¹²¹ Since alcohol content in beer advertising is prohibited in only eighteen states,¹²² much of the country can be exposed to advertisements which legally disclose alcohol content. Because advertising is a far more powerful mechanism than labeling for influencing consumers' brand choices,¹²³ the fact that alcohol content may be disclosed in advertising in so many states, but not in labeling, seems to run counter to the government's asserted interest in preventing strength wars.

Furthermore, the Court noted that the government's assertions about the likelihood of strength wars arising from alcohol content labeling

118. *Id.* (quoting *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 341 (1986)).

119. *See id.* at 1593 ("[T]he irrationality of this unique and puzzling regulatory framework ensures that the labeling ban will fail to achieve [the government's] end."); *see also* *City of Ladue v. Gilleo*, 114 S. Ct. 2038, 2044 (1994) ("Exemptions from an otherwise legitimate regulation . . . may diminish the credibility of the government's rationale for restricting speech in the first place."); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 715 (1984) (noting that the "selective approach" to regulation "suggests limits on the substantiality of the [government's] interests"). *But cf.* *City of Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 52-53 (1986) (rejecting claim that speech restriction was impermissibly underinclusive for singling out adult theaters).

120. *See Coors*, 115 S. Ct. at 1592. BATF's implementing regulations were previously discussed in Part I.A.

121. *See* 27 U.S.C. § 205(f)(2) (1994); 27 C.F.R. § 7.50 (1994).

122. *Coors*, 115 S. Ct. at 1592.

123. *See* DAVID N. MARTIN, *ROMANCING THE BRAND: THE POWER OF ADVERTISING AND HOW TO USE IT* 153 (1989); Anthony Tennant, *Creating Brand Power*, in *BRAND POWER* 33, 35 (Paul Stobart ed., 1994). *But cf.* JOSEPH C. FISHER, *ADVERTISING, ALCOHOL CONSUMPTION, AND ABUSE: A WORLDWIDE SURVEY* 142 (1993) (finding "[n]o experimental evidence" that advertising affects overall levels of alcohol consumption).

consist mainly of “anecdotal evidence and educated guesses.”¹²⁴ The FAAA’s legislative history on this matter was scant, and the government demonstrated in its brief only a weak empirical connection between alcohol content labeling and the threat of strength wars in the current beer market.¹²⁵ This demanding search for evidence of a nexus stands in marked contrast to the traditional deference extended by the Court to congressional judgments of this sort.¹²⁶ Indeed, *Coors* suggests even less deference under the third prong than was extended to state and local governments in some of the earlier cases.¹²⁷ Thus, the lack of evidence to support the asserted link between labeling and strength wars, combined with the irrationality of the regulatory scheme for alcoholic beverage labeling and advertising, led the Court to conclude that the FAAA’s labeling restriction failed under *Central Hudson*’s third prong.¹²⁸

Finally, in dicta, the Court opined that the prohibition on the disclosure of alcohol content in labeling would also fail the fourth prong of the test. *Coors* suggested a series of less restrictive alternatives for achieving the governmental interest, such as prohibiting promotional

124. *Coors*, 115 S. Ct. at 1593.

125. *See id.* *Coors* had argued that such consumer behavior occurs only in the malt liquor segment of the market, but the initial marketing experience with ice beer appears to contradict this argument. Pending the outcome of the *Coors* litigation, the government stayed enforcement of Section 205(e)(2) of the FAAA. *See supra* note 8. Ice beers were first introduced in the market after this stay of enforcement, so they are the first beer products to include alcohol content information on their labels. A recent article suggests that some consumers will intentionally purchase higher alcohol content beer if this information is disclosed. *See Anheuser-Busch to Revamp Its Ice Draft Beer Product*, WALL ST. J., Feb. 17, 1995, at B9 (“Stung by competitive products with slightly more kick, [Anheuser-Busch] said it is reluctantly increasing the alcohol content to 5.5% from 5% to match other ice beers”); *see also* Adolph Coors Co. v. Brady, 944 F.2d 1543, 1549 (10th Cir. 1991) (noting *Coors*’ admission that its primary motivation for disclosing alcohol content was to dispel public perception that its beers are weaker than competing brands).

126. *See, e.g.,* United States v. Edge Broadcasting Co., 113 S. Ct. 2696, 2703-05 (1993) (upholding 1934 federal statute which prohibited broadcasts of lottery advertisements); San Francisco Arts & Athletics, Inc. v. United States Olympic Comm., 483 U.S. 522, 539 (1987) (“Congress reasonably could conclude that most commercial uses of the Olympic words and symbols are likely to be confusing.”); *supra* note 101 (discussing Equal Protection decisions).

127. *See* *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 342-44 (1986) (deferring to legislative judgment that casino advertising restrictions would limit gambling by citizens); *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (plurality) (“hesitat[ing] to disagree with the accumulated, common-sense judgments of local lawmakers”); *see also* *City of Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 51-52 (1986) (“The First Amendment does not require a city . . . to conduct new studies or produce evidence independent of that already generated by other cities, so long as whatever evidence the city relies upon is reasonably believed to be relevant to the problem that the city addresses.”).

128. *Coors*, 115 S. Ct. at 1592 (quoting *Edenfield*, 113 S. Ct. at 1798).

efforts which emphasize alcohol strength, limiting the labeling ban to malt liquors, or capping the maximum alcohol content of beers.¹²⁹ Accepting these alternatives as reasonable, the Court concluded that the regulation was not adequately tailored to the attainment of the government's goal.¹³⁰

A few months after it decided *Coors*, the Court once again addressed the issue of appropriate commercial speech protection for attorney advertising. In *The Florida Bar v. Went For It, Inc.*,¹³¹ it considered the constitutionality of a prohibition against targeted direct mail solicitation of accident victims or their families within thirty days of an accident or disaster. In a sharply divided decision that turned largely on conflicting assessments of the evidence offered in support of the asserted link between ends and means, the Court upheld the ban.¹³² Relying on the extensive record submitted by The Florida Bar in support of the rule,¹³³ and purporting to follow the gloss on the nexus requirements

129. See *id.* at 1593. The Court soon may have the opportunity to elaborate more directly on the fourth prong. See *44 Liquormart, Inc. v. State of Rhode Island*, 39 F.3d 5, 7-8 (1st Cir. 1994) (rejecting First Amendment challenge to state statutes which forbid any alcoholic beverage price advertising except at the point of sale), *cert. granted*, 115 S. Ct. 1821 (1995). The First Circuit held that the ban on price advertising would directly advance the state's substantial interest in promoting temperance. See *id.* at 7-8 (noting that, although there was conflicting expert testimony and no empirical evidence, "there would seem inherent merit in the State's contention that competitive price advertising would lower prices, and that with lower prices there would be more sales," adding that "[a]dvertising must be generally productive, or so much money would not be spent on it"). Moreover, the court thought that state advertising restrictions deserved a presumption of validity because of the Twenty-First Amendment. See *id.* Finally, under *Central Hudson's* fourth prong, the First Circuit dismissed the argument that the same goal could be achieved more directly by setting minimum prices or increasing the sales tax on alcoholic beverages. See *id.* at 7 ("[T]he State is entitled to a reasonable choice."); see also *infra* note 233; *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1313-17 (4th Cir. 1995) (upholding city ordinance prohibiting alcohol advertising on billboards in certain locations), *petition for cert. filed*, 64 U.S.L.W. 3333 (U.S. Oct. 27, 1995) (No. 95-685).

130. *Coors*, 115 S. Ct. at 1593; see also *id.* at 1597 (Stevens, J., concurring in judgment) ("Any 'interest' in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment . . ."). Another alternative mentioned by Justice Stevens, *id.* at 1594-95, is a "counter speech" approach, see *Central Hudson*, 447 U.S. at 571, such as the warning statement recently mandated by Congress. See *Alcoholic Beverage Labeling Act of 1988*, Pub. L. No. 100-690, tit. VIII, § 8001(a)(3), 102 Stat. 4518 (codified at 27 U.S.C. §§ 213-219 (1994)); see also Steve Younger, Comment, *Alcoholic Beverage Advertising on the Airwaves: Alternatives to a Ban or Counteradvertising*, 34 UCLA L. REV. 1139, 1190 (1987) ("Congress should seek to burden the product rather than the medium in which it is advertised").

131. 115 S. Ct. 2371 (1995).

132. See *id.* at 2376-81.

133. See *id.* at 2377-78. The Florida Bar submitted a lengthy summary of its two-year study of lawyer advertising and solicitation containing both statistical and anecdotal data to

announced in *Coors*, the majority concluded that the limited advertising prohibition “targets a concrete, nonspeculative harm.”¹³⁴ Thus, the Supreme Court’s decisions from the latest Term demand some proof that government restrictions on commercial speech directly advance a substantial interest, but the precise quantum of evidence required remains unclear.

III. IMPLICATIONS FOR PRODUCT LABELING CONTROLS

The Court’s decision in *Coors* is important for a number of reasons. At a basic level, the unanimous decision to strike down the labeling restriction confirms the notion that commercial speech receives some meaningful protection under the First Amendment. The backsliding apparent in *Posadas*, for instance, was merely a temporary aberration and not a signal that the Court was reconsidering the validity of this new category of protected speech. On the contrary, the noticeable absence in *Coors* of the traditional deference extended to Congress suggests a heightened concern for commercial speech. In part, the Court appeared to be responding to a problem of regulatory obsolescence.¹³⁵ In doing so, it put some teeth into the nexus requirements of the *Central*

demonstrate that the public views direct-mail solicitation of accident victims and their families as intrusive and reflecting poorly on the legal profession. *See id.* The dissenting members of the Court took particular issue with the majority’s acceptance of this study as evidence of a nexus. *See id.* at 2384 (Kennedy, J., dissenting) (“This document includes no actual surveys, few indications of sample size or selection procedures, no explanations of methodology, and no discussion of excluded results.”).

134. *Id.* at 2378 (emphasizing that no effort had been made to refute The Florida Bar’s study). In contrast, the Court in *Coors* regarded the government’s fear of strength wars as highly speculative, both because BATF failed to offer anything other than “anecdotal evidence and educated guesses” in support of a nexus and because *Coors* had made some attempt to refute the claimed connection. *See Coors*, 115 S. Ct. at 1593; *see also Shapero v. Kentucky Bar Ass’n*, 486 U.S. 466, 475 (1988).

135. *See Coors*, 115 S. Ct. at 1590-93; *City of Cincinnati v. Discovery Network, Inc.*, 113 S. Ct. 1505, 1510 (1993) (“The ordinance on which [the City] relied was an outdated prohibition against the distribution of any commercial handbills on public property”); *Nashville, C. & S.L. Ry. v. Walters*, 294 U.S. 405, 415 (1935) (“A statute valid when enacted may become invalid by change in the conditions to which it is applied.”). *But cf. Walters v. National Ass’n of Radiation Survivors*, 473 U.S. 305, 319-35 (1985) (rejecting due process and First Amendment challenges to civil war era statute which capped attorneys’ fees in veterans’ benefits claim proceedings at \$10); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71 (1983) (“[T]he insufficiency of the original motivation does not diminish other interests that the restriction may now serve.”). Although the Court in *Radiation Survivors* suggested that “more deference is called for [where] the statute in question for all relevant purposes has been on the books for over 120 years,” 473 U.S. at 319, it also explained that Congress had recently, though ambiguously, reaffirmed its interest in preventing the unnecessary diversion of veterans’ benefits to attorneys. *See id.* at 322.

Hudson test, making the third prong more than a formality. Finally, *Coors* represents the Court's first commercial speech decision directly to address product labeling controls. As such, it may have important implications for other federal limitations on the inclusion of truthful information in labeling.

A. Health Claims in Food Labeling

The FDA's preambles to both the nutrient content claim and health message regulations include a detailed response to industry complaints that the proposed restrictions would violate the First Amendment.¹³⁶ The mere inclusion of these lengthy defenses is telling. Close scrutiny of the FDA's legal arguments reveals, however, the weakness of the Agency's constitutional position, a weakness compounded by the Court's intervening decisions from the last few Terms. Although the FDA apparently took comfort in the fact that Congress specifically directed it to promulgate many of these new rules,¹³⁷ this cannot insulate the regulations or, for that matter, the statute itself from searching judicial scrutiny under the First Amendment.

A few commentators have applauded the FDA's nutrition labeling requirements as consonant with First Amendment ideals because they promote the availability of information that market forces otherwise would not provide in sufficient quantities.¹³⁸ Even if one agrees, however, that government prompting sometimes may be necessary to ensure that consumers receive useful information about products, overly stringent limitations on the provision of truthful¹³⁹ information work

136. See 58 Fed. Reg. 2302, 2392-97 (1993) (nutrient content claims); 58 Fed. Reg. 2478, 2524-28 (1993) (health claims); see also 59 Fed. Reg. 395, 421-24 (1994) (health claims for dietary supplements). This section of the Article focuses on the preamble accompanying the health claims regulations but includes any significant additional points made in the other two.

137. See, e.g., 58 Fed. Reg. at 2396. Although an agency cannot decline to implement a statutory provision which it regards as unconstitutional, it must take First Amendment issues into account when choosing between permissible interpretations of a statute. See *National Treasury Employees Union v. Federal Labor Relations Auth.*, 986 F.2d 537, 539-40 (D.C. Cir. 1993).

138. See, e.g., Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653, 662 (1993); see also Meir Dan-Cohen, *Freedoms of Collective Speech: A Theory of Protected Communications by Organizations, Communities, and the State*, 79 CAL. L. REV. 1229, 1244-48 (1991); Daniel A. Farber, *Free Speech Without Romance: Public Choice and the First Amendment*, 105 HARV. L. REV. 554, 568-79 (1991).

139. It is, of course, inaccurate to speak in terms of scientific "truth." See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993) ("Scientific conclusions are subject to perpetual revision."). Unlike objectively verifiable statements of alcohol content, biomedical knowledge is contingent and rapidly changing. See Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 753-66 (1994). Even so, if properly qualified (see, e.g., text accompanying *supra* note 27), health

to undermine the "marketplace of ideas" promoted by the First Amendment. Federal regulators, in their zeal to protect the public from potentially misleading labeling or advertising, should not unduly interfere in that marketplace or squelch information concerning consumer products. Concern over individual abuses, which undoubtedly exist,¹⁴⁰ should not inspire overbroad restrictions that impede the flow of accurate and useful information. In light of the *Coors* decision, the FDA's broad restrictions on health claims in food labeling may be vulnerable to constitutional challenge.¹⁴¹

1. Is Food Labeling Protected Commercial Speech?

In the preamble accompanying its final regulations, the FDA suggested that health claims on food labels do not constitute protected commercial speech at all.¹⁴² Courts have, however, clearly regarded information or claims appearing in product labeling as commercial speech.¹⁴³ Although it was not asked to decide the issue, the Supreme Court in *Coors* noted that "[b]oth parties agree that the information on beer labels constitutes commercial speech" and proceeded to subject the labeling ban in question to a *Central Hudson* analysis.¹⁴⁴ By contrast, some have argued that, because they contain scientific information of

claims can be regarded as no less truthful than purportedly quantitative measurements. *Cf.* *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 42 (D.C. Cir. 1985) (holding that quantitative "low tar" cigarette claims based on an unrecognized testing method were deceptive).

140. *See, e.g.*, Kim Painter, *Some Food Labels Branded Deceptive*, USA TODAY, Aug. 2, 1995, at 1D.

141. Several challenges to the health claims regulations applicable to dietary supplements are currently pending. *See, e.g.*, *Wellife Prods. v. Shalala*, 52 F.3d 357, 359 (D.C. Cir. 1995) (transferring constitutional challenge to district court); *Mineral Resources Int'l v. Shalala*, 53 F.3d 305, 308-09 (10th Cir. 1995) (same); *National Council for Improved Health v. Shalala*, 893 F. Supp. 1512, 1517-20 (D. Utah 1995) (rejecting First Amendment challenge). Producers of wine have hinted at a challenge to BATF's absolute prohibition against health claims on certain alcoholic beverages notwithstanding growing scientific evidence that moderate consumption of red wine in particular may reduce the risk of heart disease. *See* Brief Amicus Curiae of the Wine Institute in Support of Respondent at 5-9, *Coors* (No. 93-1631); *see also* *Group Wants Alcohol Labels to List Benefits*, GAINESVILLE SUN, May 10, 1995, at 9A.

142. *See* 58 Fed. Reg. at 2525 ("[L]abeling does not fall clearly within the bounds of commercial speech.").

143. *See, e.g.*, *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991) ("Product labels, which are part of a firm's marketing plan to provide certain information to the consumer, also constitute commercial speech."), *aff'd after remand*, 2 F.3d 355 (10th Cir. 1993), *aff'd*, 115 S. Ct. 1585 (1995); *see also* *Hornell Brewing Co. v. Brady*, 819 F. Supp. 1227, 1233 (E.D.N.Y. 1993); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986).

144. *Coors*, 115 S. Ct. at 1589-93; *cf.* *Kordel v. United States*, 335 U.S. 345, 351 (1948) (In broadly construing statutory term "labeling," the Court observed that "[e]very labeling is in a sense an advertisement.").

clear public interest, health claims are entitled to greater protection under the First Amendment than mere commercial speech.¹⁴⁵ But the FDA categorically rejected this notion.¹⁴⁶ Even if health messages in food labeling are considered nothing more than commercial speech, these promotional statements are entitled to some First Amendment protections so long as they are not false or misleading.

The FDA conceded that "parts of the [NLEA] and these regulations may have an incidental effect on speech in a narrowly defined area,"¹⁴⁷ but it argued that the government did not thereby forfeit its power to regulate economic activities over which it exerts "extensive regulatory authority."¹⁴⁸ Although poorly articulated, the Agency may have been arguing that the greater power (in this case, the power to prohibit the sale of particular products) includes the lesser power (here, to prohibit certain labeling claims about such products),¹⁴⁹ a view championed by the majority in *Posadas*.¹⁵⁰ *Central Hudson* does not, of course,

145. See, e.g., 58 Fed. Reg. at 2527; Martin H. Redish, *Product Health Claims and the First Amendment: Scientific Expression and the Twilight Zone of Commercial Speech*, 43 VAND. L. REV. 1433, 1437 (1990) ("Such speech appropriately is viewed not as commercial, but rather as fully protected scientific expression."); see also *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983) (noting that where "a speaker desires to convey truthful information relevant to important social issues . . . the First Amendment interest served by such speech [is] paramount").

146. See 58 Fed. Reg. at 2527 ("A label is not entitled to the protection due noncommercial speech simply because it contains a discussion of an issue of broad public interest.").

147. *Id.* at 2525.

148. *Id.* (noting that the government "'does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity'" (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978))). The holding in *Ohralik* does not, however, support the FDA's contention that speech in areas of extensive regulation is accorded no constitutional protection. Although it had not yet developed the *Central Hudson* test, the Court clearly approached lawyer solicitation as a form of commercial speech. See *Ohralik*, 436 U.S. at 455-57.

149. See 58 Fed. Reg. at 2524-25 ("The [NLEA] amended the act to permit certain information about the relationship of nutrients in food and disease to appear on a food label without misbranding the food under section 403 of the act or transforming it into a drug under section 201(g)(1)(B) of the act. The regulations implementing these amendments thus permit more information on food labels than has previously been allowed under the act."); see also *Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex.) ("Texas could ban the sale of all food products containing psyllium, and Kellogg could not claim a free speech right to sell such a product. . . . A requirement that the [health] claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product."), *aff'd mem.*, 940 F.2d 1530 (5th Cir. 1991).

150. See *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 345-46 (1986) (though still applying the *Central Hudson* test). For a well-reasoned critique of this logic, see Sylvia A. Law, *Addiction, Autonomy, and Advertising*, 77 IOWA L. REV. 909, 938-42 (1992); see also *Coors*, 115 S. Ct. at 1589-90 n.2 (rejecting government's suggestion that it has "broader

entirely divest agencies of the power to regulate whenever speech is impacted, but it does place a heightened burden of justification on the government in such circumstances. *Coors* itself should put to rest any claim that agencies are free to subject companies in heavily regulated industries to whatever restrictions on the disclosure of information that seem necessary in the pursuit of their delegated responsibilities.¹⁵¹

2. Are Health Claims Inherently Misleading?

Seemingly recognizing the weakness of its first line argument that food labeling is not protected commercial speech, the FDA proceeded to apply the *Central Hudson* test.¹⁵² Under the first prong,¹⁵³ the speech must concern a lawful activity and not be misleading. The Agency asserted that health claims are "inherently misleading."¹⁵⁴

latitude to regulate speech that promotes socially harmful activities"); *City of Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 763 (1988). Even so, in its recent proposal to restrict advertising for tobacco products, the FDA observed that it has "greater leeway" to regulate "speech with regard to socially harmful activities." 60 Fed. Reg. 41,314, 41,355 (1995) (adding that *Coors* is not contrary).

151. The FDA cited a number of decisions for the proposition that companies in heavily regulated industries cannot object to incidental restrictions on speech. *See* 58 Fed. Reg. at 2525; *see also* *The Florida Bar v. Went For It, Inc.*, 115 S. Ct. 2371, 2381 (1995) ("Particularly because the standards and conduct of state-licensed lawyers have traditionally been subject to extensive regulation by the States, it is all the more appropriate that we limit our scrutiny . . ."). These decisions are easily distinguished from the FDA's health claims restrictions. *See, e.g., Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 758 n.5 (1985) (plurality) (dictum describing varieties of commercial speech); *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 912 (1982) (dictum in case involving politically-motivated boycott, noting that regulation of economic activity having an incidental effect on speech is permissible if there is a strong government interest at stake); *SEC v. Wall Street Publishing Inst., Inc.*, 851 F.2d 365, 373-74 (D.C. Cir. 1988) (conceding that "it would be an overstatement to assert that the First Amendment does not *limit* regulation in the securities field," the court upheld the SEC's power to enforce a statutory disclosure requirement to prevent misunderstandings by investors), *cert. denied*, 489 U.S. 1066 (1989); *SEC v. Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (rejecting, after applying the *Central Hudson* test, challenge to temporary injunction issued by the SEC against an investment adviser's blatantly false advertisements); *see also infra* note 155 (distinguishing lower court decisions which rejected First Amendment challenges to the FDA's regulation of food labeling).

152. *See* 58 Fed. Reg. at 2526-27. The FDA did acknowledge, for instance, that any dietary guidance statements appearing on labels would be commercial speech, noting that "[l]abeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would 'propose' such a transaction." *Id.* at 2527.

153. As noted previously, *supra* note 67, the Court's most recent opinions seemingly modify the four-part *Central Hudson* analysis to create a threshold test followed by three prongs. Nonetheless, for the sake of clarity, this section abides by the four-part framework originally set out in *Central Hudson*.

154. *See* 58 Fed. Reg. at 2526 (noting that "particular attributes of health claims on the

Citing a number of lower court decisions,¹⁵⁵ the FDA argued that it freely may limit the content of product labeling under the statutory prohibitions against the misbranding of food products.¹⁵⁶ Ironically, one reason that the Agency viewed health claims as inherently misleading was their "great importance to the public,"¹⁵⁷ an explanation which

food label make them inherently misleading"). The government initially had made a similar argument in the Coors litigation—namely, that alcohol content disclosure was "inherently misleading"—but failed to pursue this point on appeal. *See Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1547 n.2 (10th Cir. 1991). Curiously, the FDA did not make this argument in defending the constitutionality of its proposed restrictions on tobacco advertising. *See* 60 Fed. Reg. at 41,354 ("The *Central Hudson* analysis begins with the second prong.").

155. *See Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex.) (holding, on request for preliminary injunction, that food manufacturer was not likely to prevail on its First Amendment claim because the State's detentions of a product on adulteration and misbranding grounds "only restrain the ability of the distributors who received the detention order to sell the product"), *aff'd mem.*, 940 F.2d 1530 (5th Cir. 1991); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986) (holding that the substantial government interest in prohibiting deceptive labeling justified the "extremely narrow encroachment" on commercial speech caused by FDA sanctions against the distributor of a dietary supplement); *United States v. Articles of Food . . . Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975) (summarily rejecting manufacturer's proposed First Amendment defense to seizure of its food products for false and misleading statements in its labeling); *United States v. Articles of Drug*, 32 F.R.D. 32, 34-35 (S.D. Ill. 1963) (sustaining the FDA's statutory authority to seize copies of a book used as false and misleading labeling for vitamin and mineral products, and rejecting First Amendment objection because the seizure did not affect the book's availability to interested readers); *United States v. 8 Cartons, Containing . . . Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951) (same); *see also Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495-96 (1982) (rejecting First Amendment challenge to ordinance regulating the sale of drug-paraphernalia within a certain proximity of any literature encouraging illegal drug use).

156. 58 Fed. Reg. at 2525. Previously, the FDA prohibited all health claims on food products, *see supra* note 19, but not necessarily on the theory that such claims would misbrand the food. Instead, the Agency took the position that therapeutic claims would affect the product's regulatory classification, converting an erstwhile food into a drug. *See, e.g., Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 337-38 (7th Cir. 1983); *United States v. An Article of Drug . . . Honey*, 218 F. Supp. 208, 211 (E.D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965). Health claims could still have been made for such a "drug" product, but only if the manufacturer satisfied the FDA's strict new drug approval requirements. *See* 21 U.S.C. § 355 (1994); 21 C.F.R. pt. 314 (1994); *see also* Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 6-10 (1995) (summarizing the new drug approval requirements).

157. 58 Fed. Reg. at 2526 ("Because health claims are of great importance to the public, they have a great potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce consumer purchases may take on increased importance in the mind of the public and thus be more likely to mislead."). Another reason includes consumers' assumptions that the Agency has verified all information in the label. *Id.*; *see also American Home Prods. Corp. v. FTC*, 695 F.2d 681, 698 (3d Cir. 1982). If this sufficed to eliminate First Amendment protections, however, then any information disclosures in highly regulated industries might be vulnerable to government prohibitions.

seems to reinforce rather than weaken the underlying claim for First Amendment protection.¹⁵⁸ At its base, the FDA's position that unapproved health claims are "inherently misleading" appears to represent a simple policy judgment rather than an empirically-based conclusion.¹⁵⁹

Individual enforcement actions against products whose labeling includes misleading claims undoubtedly are permissible, in part because the government shoulders the burden of proof in these proceedings.¹⁶⁰ But the First Amendment does not authorize broad prophylactic rules against truthful claims merely because they may have some undefined potential to mislead consumers.¹⁶¹ For instance, one lower court held unconstitutional a state restriction on the use of the term "butter" in advertising for butter substitutes because the limitation applied without regard to whether the use of that term was misleading in the particular case.¹⁶² In response to industry comments citing this decision, the FDA relied on congressional concerns over the use by some manufacturers of inaccurate or ambiguous nutrient content claims or scientifically unfounded health messages.¹⁶³

In spite of the Agency's arguments to the contrary, health claims on foods are not "inherently" misleading. In the wake of *Coors*, if a manufacturer wishes to make a truthful and carefully qualified claim, the FDA should not be able to prohibit that claim unless it can demonstrate some reasonable likelihood that consumers might be misled. Instead, the Agency offered the tautological argument that a claim is intrinsically

158. See *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983).

159. Cf. Richard Craswell, *Interpreting Deceptive Advertising*, 65 B.U. L. REV. 657, 659-60 (1985).

160. See, e.g., *United States v. An Article of Food . . . "Diet Thins,"* 377 F. Supp. 746, 748-49 (E.D.N.Y. 1974) (noting that the government must prove that label representation is either false or misleading); see also *United States v. 60 28-Capsule Bottles . . . "Unitrol,"* 325 F.2d 513 (3d Cir. 1963). Of course, the courts often defer to an agency's expert judgment that a claim is likely to mislead consumers. See, e.g., *Kraft, Inc. v. FTC*, 970 F.2d 311, 318-20 (7th Cir. 1992), *cert. denied*, 113 S. Ct. 1254 (1993).

161. See 58 Fed. Reg. 2302, 2395 (1993) ("Some comments argued that the requirement that the proponent of an undefined claim submit a petition for its approval unconstitutionally shifts the burden of distinguishing misleading and nonmisleading speech from the Government to the speaker."); see also *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985) ("Were we to accept the State's argument in this case, we would have little basis for preventing the government from suppressing other forms of truthful and nondeceptive advertising simply to spare itself the trouble of distinguishing such advertising from false or deceptive advertising."); *Association of Nat'l Advertisers v. Lungren*, 809 F. Supp. 747, 756 (N.D. Cal. 1992) (explaining that "a legislative body cannot justify its restrictions on commercial speech simply by declaring that marketing claims are misleading"), *aff'd*, 44 F.3d 726, 731-32 (9th Cir. 1994), *cert. denied*, 116 S. Ct. 62 (1995).

162. See *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 652-53 (S.D. Ohio 1989).

163. See 58 Fed. Reg. at 2395-96.

misleading if not pre-approved by the FDA because the use of such an unapproved claim would constitute a misbranding violation under the statute.¹⁶⁴ The Agency simply noted that "Congress chose to permit only those health claims on food that FDA determines to be scientifically valid, effectively recognizing that health claims are so potentially misleading as to be inherently misleading."¹⁶⁵ Such a generalized and impressionistic finding of past abuses cannot, however, suffice to allow legislators or regulators to announce that any unapproved but truthful claims are prohibited because of the risk that some other claims could mislead some consumers.

Thus, although the government may have a substantial interest in combatting potentially misleading claims, its remedial choice must be evaluated under the nexus requirements of the *Central Hudson* test. There is simply no merit to the FDA's effort to pretermitt that analysis by characterizing unapproved health claims as inherently misleading under the first prong. While it is true that the commercial speech at issue here has the potential to mislead some consumers and has been abused in the past, it does not follow that health claims as a class of speech are inherently misleading and, therefore, wholly unprotected by the First Amendment.

3. Are the Government's Interests Substantial?

Applying *Central Hudson's* second prong, the government's interest in regulating health claims to promote public health is undeniably substantial.¹⁶⁶ The Court also has recognized the government's interest in "insuring that the stream of commercial information flow cleanly as well as freely."¹⁶⁷ More precisely, the FDA argued that consumers have a First Amendment interest in obtaining information on which to base choices about product purchases and that this interest is " 'served

164. *See id.* at 2525 ("Because FDA case law makes clear that a label statement that misbrands a food product is not subject to First Amendment protection, an unapproved health claim on a food label would not be protected speech.").

165. *Id.* at 2526 ("Experience had shown that many 'unfounded' health claims were being used on foods."). In attempting to argue that health claims are inherently misleading, the FDA also relied on *In re R.M.J.*, 455 U.S. 191, 203 (1982), claiming that speech which "experience has proved . . . is subject to abuse" is unprotected under the First Amendment. 58 Fed. Reg. at 2526. But the Court struck down the attorney advertising restrictions which were at issue in *R.M.J.*, finding no nexus between the restriction and a substantial state interest. *See* 455 U.S. at 206-07.

166. *See Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 341 (1986).

167. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 (1976).

by insuring that the information is not false or deceptive.’ ”¹⁶⁸ At one point in the preamble, the Agency referred to “the Government’s interest in ensuring the scientific validity of health claims on the food label.”¹⁶⁹ But surely this is a substantial interest only insofar as it furthers the interest in protecting consumers from false and misleading claims; the FDA is not a peer review mechanism for the scientific community.

Evidently, Congress was concerned that consumers might be misled by unregulated health claims and the consequent impact these claims might have on public health and safety.¹⁷⁰ Its concern was tempered, however, by a countervailing interest in maximizing the disclosure of information about nutrition and health.¹⁷¹ Indeed, as the Court noted in *Coors*, the NLEA reflects a preference for informing consumers about the relationship between diet and health.¹⁷² The Agency itself has acknowledged that “consumers will lose valuable information” if truthful health claims are withheld from the public.¹⁷³

168. 58 Fed. Reg. at 2526 (citing *National Comm’n on Egg Nutrition v. FTC*, 570 F.2d 157, 162 (7th Cir. 1977), in support of this proposition, *cert. denied*, 439 U.S. 821 (1978)). Although the court in *Egg Nutrition* recognized the government’s interest in protecting consumers, it also required that the FTC order, which mandated that the industry include opposing scientific studies in its advertisements whenever making positive health claims about eggs, be modified to conform with First Amendment requirements. *See Egg Nutrition*, 570 F.2d at 164 (noting that the First Amendment prevents the FTC from imposing a remedy against false or misleading speech which was broader than necessary to accomplish its goal of preventing consumer deception).

169. 58 Fed. Reg. at 2525; *see also* 59 Fed. Reg. 395, 422 (1994) (asserting that the “FDA’s regulation of health claims in labeling bears a specific relationship to the interests the agency has asserted because it is directed specifically at ensuring the reliability and validity of these claims”).

170. *See* 58 Fed. Reg. at 2526.

171. *See supra* note 18; *see also* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(13), 108 Stat. 4326 (finding that, “although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers”).

172. *See Coors*, 115 S. Ct. at 1590-91. The *Coors* Court did, however, apparently concede that the government could have a substantial interest in altering consumers’ behavior by denying them access to information which itself was neither false nor misleading. *See id.* at 1591 (“[T]he Government here has a significant interest in protecting the health, safety, and welfare of its citizens by preventing brewers from competing on the basis of alcohol strength, which could lead to greater alcoholism and its attendant social costs.”). The Court explained that previously, in *Posadas*, “we found that the Puerto Rico Legislature’s interest in promoting the health, safety, and welfare of its citizens by reducing their demand for gambling provided a sufficiently ‘substantial’ governmental interest to justify the regulation of gambling advertising.” *Id.*

173. 56 Fed. Reg. 60,856, 60,869 (1991) (In its initial Regulatory Impact Analysis, the FDA recognized that, “if [health] claims that are likely to be true are removed, this will decrease the

It is simply inaccurate, therefore, to focus exclusively on the undoubted legislative concern that consumers not be duped by false or misleading labeling claims. The fundamental question remains whether the restriction is tailored to accomplish the government's stated ends without taking any one of those goals out of context and assigning it exaggerated weight in the calculus. After its lengthy attempt to avoid having to undertake the *Central Hudson* test, however, the Agency's preamble gives scant attention to explaining how its regulations satisfy the nexus requirements, dismissing this task with a few conclusory sentences.¹⁷⁴

4. Do the Restrictions Advance Those Interests?

Under *Central Hudson*'s third prong, the health claims restrictions must directly advance the government's substantial interests.¹⁷⁵ In *Coors*, which struck down the prohibition against alcohol content disclosure under prong three, the Court emphasized that the government has the burden of showing that the regulation at issue advances its asserted interests "in a direct and material way."¹⁷⁶ Most importantly, *Coors* demanded evidence to support the judgment that a particular restriction will achieve the government's purposes. Apart from citing the floor statements of a few members of Congress,¹⁷⁷ which are surely nothing more than the "anecdotal evidence and educated guesses" rejected as inadequate in *Coors*,¹⁷⁸ the FDA failed to identify anywhere

total benefits of the 1990 amendments as consumers will lose valuable information."); *see also* 60 Fed. Reg. 66,206, 66,214 (1995) ("The agency has no desire for its regulations to unnecessarily stand in the way of the use of health claims and the presentation of the important information contained therein."). Indeed, for several decades, notwithstanding growing evidence of an association with coronary heart disease, the Agency had prohibited any reference to cholesterol in food labeling. *See* 24 Fed. Reg. 9990 (1959).

174. *See* 58 Fed. Reg. at 2526-27.

175. *See* *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 564 (1980) (requiring that "the regulatory technique must be in proportion to that interest" and must "be designed carefully to achieve the State's goal").

176. *Coors*, 115 S. Ct. at 1592 (internal quotation marks omitted); *see also* *Ibanez v. Florida Dep't of Business & Professional Regulation*, 114 S. Ct. 2084, 2090 (1994) (refusing to "allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden").

177. *See* 58 Fed. Reg. at 2526; 58 Fed. Reg. 2302, 2393-94 (1993).

178. *See* *Coors*, 115 S. Ct. at 1593; *see also* *Turner Broadcasting Sys. v. FCC*, 114 S. Ct. 2445, 2470-72 (1994) (plurality) (remanding First Amendment challenge to 1992 cable statute notwithstanding lengthy congressional hearings and detailed findings, including reliance on a study conducted by the FCC); *Edenfield v. Fane*, 113 S. Ct. 1792, 1800 (1993) (explaining that the government's "burden is not satisfied by mere speculation or conjecture"). The FDA already has taken some comfort, however, in the *Went For It* majority's willingness to accept anecdotal

in its otherwise thorough preambles any evidence to suggest that its demanding requirements are likely to reduce a risk of consumer deception.

One must also assess the purported linkage between the health claims restrictions and the government's broader public health purpose associated with providing consumers new information about the relationship between diet and health. The effect of the regulations is to deprive consumers of this very information, except in extremely limited circumstances in which the FDA has approved a health claim. There appears to be no direct connection between the suppression of unapproved but truthful health claims, and the protection of public health. Moreover, prohibiting the use of an approved claim on a product simply because it contains a disqualifying level of some other nutrient that the FDA regards as unhealthy (e.g., sodium) has absolutely nothing to do with the potential for the health claim to mislead consumers, though the Agency expressed concerns that a truthful health claim may lead consumers to believe that the product is healthy in all respects.¹⁷⁹ This expansive notion seems inconsistent with the Supreme Court's repeated admonition that the First Amendment protects even incomplete information, trusting consumers to make intelligent choices.¹⁸⁰

Instead, the FDA hopes to influence consumers' choices by selectively limiting their access to product information. The Agency also speculated that, even if consumers are oblivious to the information appearing on food labels, manufacturers will have an incentive to formulate nutritionally-improved products so as to be able to make the

evidence to support a restriction on commercial speech. 60 Fed. Reg. 41,314, 41,354 (1995) (defending proposed restrictions on tobacco advertising); *see* *The Florida Bar v. Went For It, Inc.*, 115 S. Ct. 2371, 2377-78 (1995) ("The anecdotal record mustered by the Bar is noteworthy for its breadth and detail. . . . In any event, we do not read our case law to require that empirical data come to us accompanied by a surfeit of background information."). The Court was, however, sharply divided on this and other aspects of the case. *See id.* at 2384 (Kennedy, J., dissenting) ("Our cases require something more than a few pages of self-serving and unsupported statements by the State to demonstrate that a regulation directly and materially advances the elimination of a real harm when the State seeks to suppress truthful and nondeceptive speech.").

179. *See* 60 Fed. Reg. 66,206, 66,212 (1995) ("Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet, when, in fact, such foods are inconsistent with dietary guidelines."); 58 Fed. Reg. at 2528 ("Including a health claim on the label of a food that contains unhealthful levels of nutrients would be misleading . . .").

180. *See, e.g., Central Hudson*, 447 U.S. at 562 ("Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.").

approved claims.¹⁸¹ It is doubtful whether such a paternalistic regulatory scheme would pass First Amendment muster.¹⁸²

5. Do Less Restrictive Alternatives Exist?

Finally, even if the health claims restrictions arguably survive the third prong of the *Central Hudson* test, they should fail under the fourth prong. A law regulating potentially misleading advertising, designed to prevent consumer confusion, must be “no broader than reasonably necessary to prevent the deception.”¹⁸³ The FDA argued that its regulations directly advance the government’s legitimate interest in ensuring that consumers have access to information about food that is “scientifically valid, truthful, reliable, understandable, and not misleading.”¹⁸⁴ Although the highly prescriptive requirements applicable to nutrient content claims and health messages no doubt will prevent the use of false or misleading labeling claims, it is simply wrong to assert that the regulations are no more extensive than necessary to serve the government’s asserted interests.

The FDA explained that it had carefully considered alternative approaches before concluding that its regulation would best advance the

181. See 58 Fed. Reg. 2927, 2940 (1993). The FDA has done this before in mandating the use of exaggerated warnings about the risks of products containing chlorofluorocarbon (CFC) propellants, solely in the hope of influencing purchasing behavior—and, thereby, encouraging reformulation—even though the products posed no direct risks to consumers. See Noah, *supra* note 40, at 313-14.

182. See *Coors*, 115 S. Ct. at 1597 (Stevens, J., concurring in judgment) (“[T]he Constitution is most skeptical of supposed state interests that seek to keep people in the dark for what the government believes to be their own good.”); *Meese v. Keene*, 481 U.S. 465, 482 (1987) (“We wholly rejected these justifications [in *Virginia State Board*], finding that the ban was predicated upon assumptions about the reactions the public would have if they obtained the ‘wrong’ kind of information.”); *Central Hudson*, 447 U.S. at 577 (Blackmun, J., concurring) (“The Court . . . [has] resolved beyond all doubt that a strict standard of review applies to suppression of commercial information, where the purpose of the restraint is to influence behavior by depriving citizens of information.”); see also John E. Calfee, *FDA Underestimates Food Shoppers*, WALL ST. J., May 29, 1991, at A10 (criticizing paternalistic attitude underlying the FDA’s health claims restrictions).

183. *In re R.M.J.*, 455 U.S. 191, 203 (1982).

184. 58 Fed. Reg. at 2525-26. The Agency also cites a decision predating *Virginia State Board* which summarily rejected a First Amendment challenge to an FDA food labeling regulation defining certain claims as misleading. See *American Frozen Food Inst. v. Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976) (“Plaintiff’s First Amendment argument . . . is premised upon Plaintiff’s misconception that the regulations challenged proscribe truthful nonmisleading labeling and advertising. These regulations constitute the conclusion by the Commissioner that labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the Act.”), *aff’d on other grounds*, 555 F.2d 1059, 1060 (D.C. Cir. 1977) (*per curiam*).

government's substantial interests.¹⁸⁵ This may satisfy the Agency's duties under the Administrative Procedure Act,¹⁸⁶ but a self-serving statement that it has taken the required "hard look" at the rulemaking record will not insulate the health claims regulation from First Amendment scrutiny.¹⁸⁷ Although the Agency repeatedly emphasizes that its regulations do not restrict the dissemination of information through avenues other than product labeling,¹⁸⁸ even such a restrained prohibition on truthful promotional claims may be unconstitutional.¹⁸⁹

In only limited situations has the Court upheld blanket prohibitions on commercial speech, for instance as an allowable prophylactic rule to minimize the inherent risks of coercion associated with personal solicitation of potential clients by attorneys. "Unlike a public advertisement, which simply provides information and leaves the recipient free to act upon it or not, in-person solicitation may exert pressure and often demands an immediate response, without providing an opportunity for comparison or reflection."¹⁹⁰ But the labeling and advertising of consumer products, as noted in the quoted passage, differ substantially from the personal solicitation that is sometimes at issue in the lawyer advertising cases. Consumers have the opportunity to compare the

185. 59 Fed. Reg. 395, 423 (1994).

186. See 5 U.S.C. §§ 553(c), 706(2)(A) (1994); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

187. Cf. *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 108 (1990) (plurality) (refusing to defer to State's judgment so as to "insulate it from our review for constitutional infirmity").

188. See 59 Fed. Reg. at 422 ("Adequate alternative channels remain for the dissemination of scientific information. For example, regulation of the information that may appear on the food label in no way affects the ability of a scientist to publish experimental results in a journal."); see also *The Florida Bar v. Went For It, Inc.*, 115 S. Ct. 2371, 2381 (1995) ("Finding no basis to question the commonsense conclusion that the many alternative channels for communicating necessary information about attorneys are sufficient, we see no defect in Florida's regulation."). But see *id.* at 2385 (Kennedy, J., dissenting) ("The State's restriction deprives accident victims of information which may be critical to their right to make a claim for compensation for injuries. The telephone book and general advertisements may [only] serve this purpose in part . . .").

189. See *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69-70 n.18 (1983) ("[O]ne is not to have the exercise of his liberty of expression in appropriate places abridged on the plea that it may be exercised in some other place." (internal quotation marks omitted)). For example, the Court in *Coors* invalidated the labeling prohibition even though any interested consumer could have gotten alcohol content information directly from BATF. See 63 U.S.L.W. 3485 (1995) (describing exchange during oral argument between Justice Ginsburg and counsel for the government).

190. *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 457 (1978); see also *Edenfield v. Fane*, 113 S. Ct. 1792, 1803 (1993) ("The ban on attorney solicitation in *Ohralik* was prophylactic in the sense that it prohibited conduct conducive to fraud or overreaching at the outset, rather than punishing the misconduct after it occurred."); *Shapiro v. Kentucky Bar Ass'n*, 486 U.S. 466, 475 (1988) (contrasting written and personal solicitation).

relative qualities of different consumer products, including foods. Congress and the FDA designed the new format of the nutrition information label to facilitate precisely this activity.¹⁹¹ The suppression of information rarely if ever represents the most direct means for achieving a regulatory purpose (such as dampening consumer demand) which is not related to the prevention of false or misleading claims.¹⁹²

The prohibition on unapproved health claims is out of proportion to the government's asserted interests. Although this restriction will prevent consumer deception at the hands of unscrupulous commercial enterprises making false health claims, the reach of the regulation is overly broad. Congress and the FDA need not prohibit all unapproved claims in order to protect consumers; individual enforcement actions against companies which make unsubstantiated claims, as traditionally pursued by the FTC, would achieve the same end without depriving consumers of valuable information.¹⁹³ A similar point has been made in criticisms of recent state initiatives to restrict the use of "recyclable" and other environmen-

191. 58 Fed. Reg. 2302, 2396 (1993) ("Standardizing the nutrition information that appears in food labeling, including nutrient content claims, will make it easier for consumers to find, understand, and compare the information they need to make healthy eating choices.").

192. See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 569 (1980) ("Such conditional and remote eventualities simply cannot justify silencing appellant's promotional advertising."). In *Coors*, Justice Stevens took the position that, where the asserted government interest is not related to the prevention of false or misleading statements but instead relates to some collateral goal, commercial speech should be entitled to the same protections as are accorded political speech under the First Amendment. See *Coors*, 115 S. Ct. at 1594 (Stevens, J., concurring in judgment); see also *Central Hudson*, 447 U.S. at 574 (Blackmun, J., concurring) ("I seriously doubt whether suppression of information concerning the availability and price of a legally offered product is ever a permissible way for the State to 'dampen' demand for or use of the product."). But see Lowenstein, *supra* note 85, at 1237-47 (disputing claim that Court has invalidated commercial speech restrictions as paternalistic).

193. See Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 671 (1977) ("[P]rotection of consumers against advertising fraud should not be a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable competitive market process."). But see Richard M. Schmidt, Jr. & Robert C. Burns, *Proof or Consequences: False Advertising and the Doctrine of Commercial Speech*, 56 U. CIN. L. REV. 1273, 1281-82, 1290-91 (1988) (arguing that uncertainty about enforcement action impermissibly chills protected speech, and favoring the use of blanket rules or guidelines).

tal marketing claims.¹⁹⁴ Blanket prohibitions are neither necessary nor appropriate in such situations.

In *Coors*, the Court acknowledged several less restrictive regulatory alternatives that would achieve the government's asserted interest in preventing strength wars.¹⁹⁵ Similarly, there are a number of effective regulatory alternatives available to Congress and the FDA which would protect consumers from misleading or untruthful health claims on food labels. Some industry comments suggested requiring appropriate disclaimers to accompany truthful claims which might otherwise be misleading or which pertain to foods containing unacceptable levels of other nutrients.¹⁹⁶ This is precisely the type of alternative endorsed by the Court in *Zauderer*.¹⁹⁷ Although recognizing that the Supreme Court

194. See David Hoch & Robert Franz, *Eco-Porn Versus the Constitution: Commercial Speech and the Regulation of Environmental Advertising*, 58 ALB. L. REV. 441, 443-47 (1994); Peter J. Tarsney, Note, *Regulation of Environmental Marketing: Reassessing the Supreme Court's Protection of Commercial Speech*, 69 NOTRE DAME L. REV. 533, 562-73 (1994); cf. John M. Church, *A Market Solution to Green Marketing: Some Lessons from the Economics of Information*, 79 MINN. L. REV. 245, 324 (1994) ("Deceiving consumers under the guise of advertising policy is completely inconsistent with the underpinnings of consumer protection and should be avoided."). But see Jamie A. Grodsky, *Certified Green: The Law and Future of Environmental Labeling*, 10 YALE J. ON REG. 147, 183-92 (1993) (doubting that such restrictions are vulnerable to a First Amendment challenge, though preferring a federal approach).

195. See *Coors*, 115 S. Ct. at 1593 (noting that such alternatives include a prohibition on any marketing efforts which emphasize high alcohol content, prohibiting alcohol content disclosure only for malt liquors rather than all malt beverages, and limiting the alcohol content of beer); see also *City of Cincinnati v. Discovery Network, Inc.*, 113 S. Ct. 1505, 1510 n.13 (1993) ("[W]hile we have rejected the 'least-restrictive-means' test for judging restrictions on commercial speech, so too have we rejected mere rational basis review. . . . [I]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable.").

196. See 58 Fed. Reg. 2478, 2527 (1993) ("A number of comments recommended that foods exceeding a disqualifying nutrient level be allowed to bear an approved health claim if they also bear a statement disclosing the level of the disqualifying nutrient."); see also John M. Blim, Comment, *Free Speech and Health Claims Under the Nutrition Labeling and Education Act of 1990: Applying a Rehabilitated Central Hudson Test for Commercial Speech*, 88 NW. U. L. REV. 733, 766-67 (1994); Melinda L. Sidak, *Dietary Supplements and Commercial Speech*, 48 FOOD & DRUG L.J. 441, 457 (1993) (suggesting a similar disclaimer statement for unapproved health claims made on the labels of dietary supplements). In a controversial decision, Congress recently authorized an exemption from the NLEA for certain claims on dietary supplements when accompanied by a prominent disclaimer that the FDA has not evaluated the claim. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 6, 108 Stat. 4329 (codified at 21 U.S.C. § 343(r)(6) (1994)); F-D-C REPORTS ("The Tan Sheet"), Oct. 31, 1994, at 3.

197. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 652 n.14 (1985) ("[A]ll our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech."); see also Peel

has expressed a preference for disclaimers rather than prohibitions on potentially misleading speech, the FDA responded that, under the NLEA, it may allow disclaimers instead of disqualification only on a case-by-case basis where the "claim would assist consumers in maintaining healthy dietary practices."¹⁹⁸

Others have suggested replacing the premarket approval scheme for health claims with a system similar to the FTC's substantiation policy,¹⁹⁹ which requires a "reasonable basis" for product claims and is policed on a case-by-case basis.²⁰⁰ Again this was one of the alternatives endorsed by the Supreme Court in *Zauderer*.²⁰¹ Such an approach would be in keeping with lower court decisions rejecting free speech challenges to individualized FDA determinations that a particular

v. Attorney Registration & Disciplinary Comm'n, 496 U.S. 91, 109 (1990) (plurality) (noting the "presumption favoring disclosure over concealment"); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 n.24 (1976) (suggesting that it may be "appropriate to require that a commercial message . . . include such additional information, warnings, and disclaimers, as are necessary to prevent [commercial speech from] being deceptive").

198. 58 Fed. Reg. at 2528 (internal quotation marks omitted) ("In situations where the government's substantial interest in improving dietary practices would be promoted by permitting disclosure rather than disqualification, and where disclosure would ensure that the health claim was not misleading, FDA will permit disclosure instead of disqualification."). Although it recently proposed significant modifications to make the health claims regulations more flexible, the Agency once again refused to permit disclosure as a substitute for disqualification. *See* 60 Fed. Reg. 66,206, 66,224 (1995).

199. *See, e.g.,* Edward Dunkelberger & Sarah E. Taylor, *The NLEA, Health Claims, and the First Amendment*, 48 FOOD & DRUG L.J. 631, 656-57 (1993). "Because FTC policy imposes no restriction on truthful nondeceptive claims that are properly substantiated, it imposes a far lighter burden on truthful speech than does FDA policy." *Id.* at 656.

200. *See* 49 Fed. Reg. 30,999 (1984) (FTC's "Policy Statement Regarding Advertising Substantiation Program"); *see also* 16 C.F.R. pt. 260 (1995) (non-binding FTC guidelines governing environmental marketing claims); 59 Fed. Reg. 6279, 6280 (1994) (non-binding FDA guidelines governing claims that recombinant bovine growth hormone was not used in the production of milk); F-D-C REPORTS ("The Tan Sheet"), May 16, 1994, at 27 (describing the FTC's new "enforcement policy statement" which in certain limited instances allows properly qualified health claims in advertising for food products even if these claims are not approved by the FDA for use in labeling). In its preamble, the FDA specifically rejected suggestions that it adhere to case law involving the FTC. *See* 58 Fed. Reg. at 2528 ("FDA does not agree that it is bound to follow cases involving FTC's regulation of advertising and to permit labeling that presents one side of a scientific controversy, so long as there is a statement that a controversy exists."). The FDA pointed out that there are "fundamental differences" between the two agencies, characterizing the FTC as an agency concerned with economic regulation while the "FDA is a scientific agency" concerned with the public health. *Id.* Elsewhere in the preamble, however, it cites approvingly to favorable FTC precedents. *See, e.g., id.* at 2526.

201. *See Zauderer*, 471 U.S. at 649 ("The experience of the FTC is, again, instructive. . . . Given the possibility of policing the use of illustrations in advertisements on a case-by-case basis, the prophylactic approach taken by Ohio cannot stand . . .").

labeling claim was false or misleading.²⁰² Although broad-based rulemaking surely is more efficient for the Agency,²⁰³ the First Amendment may demand a more particularized regulatory approach.²⁰⁴ This is especially important because of the risk of regulatory obsolescence,²⁰⁵ particularly in contexts where scientific knowledge is subject to rapid and sometimes unpredictable shifts.²⁰⁶ In any event, all of these alternatives would reduce the burden on commercial speech while still achieving the government's primary goal of preventing consumer deception.

202. See *supra* note 155; see also 21 U.S.C. § 343(r)(6) (1994) (imposing substantiation rather than preapproval requirement for certain nutrient claims on dietary supplements); *Kraft, Inc. v. FTC*, 970 F.2d 311, 320-21 (7th Cir. 1992) (rejecting First Amendment challenge to FTC enforcement action), *cert. denied*, 113 S. Ct. 1254 (1993); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43-45 (D.C. Cir. 1985) (same); Pitofsky, *supra* note 193, at 673 (predicting that FTC enforcement activities would withstand First Amendment challenges); Tarsney, *supra* note 194, at 535-36, 568 (favoring case-by-case control over environmental marketing claims).

203. See *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 681 (D.C. Cir. 1973) ("[T]here is little question that the availability of substantive rule-making gives any agency an invaluable resource-saving flexibility in carrying out its task of regulating parties subject to its statutory mandate."), *cert. denied*, 415 U.S. 951 (1974); Mark H. Grunewald, *The NLRB's First Rulemaking: An Exercise in Pragmatism*, 41 DUKE L.J. 274, 282, 318-21 (1991); see also 58 Fed. Reg. 2302, 2396 (1993) (arguing that the NLEA forced the FDA to issue nutrient content claim regulations rather than adjudicate individual cases under its existing misbranding authority).

204. See *Riley v. National Fed'n of the Blind*, 487 U.S. 781, 795 (1988) ("If [case-by-case enforcement] is not the most efficient means of preventing fraud, we reaffirm simply and emphatically that the First Amendment does not permit the State to sacrifice speech for efficiency."); *Central Hudson*, 447 U.S. at 571 n.13 (suggesting a screening procedure for advertisements as less restrictive than a flat prohibition); see also *Stanley v. Illinois*, 405 U.S. 645, 656 (1972) ("[T]he Constitution recognizes higher values than speed and efficiency.").

205. See Jonathan R. Macey, *Administrative Agency Obsolescence and Interest Group Formation: A Case Study of the SEC at Sixty*, 15 CARDOZO L. REV. 909, 910-21 (1994); Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1151-52 (1988); see also *supra* note 135 (canvassing the Supreme Court's treatment of the passage of time when resolving constitutional challenges to government restrictions on speech); Richard Neely, *Obsolete Statutes, Structural Due Process, and the Power of Courts to Demand a Second Legislative Look*, 131 U. PA. L. REV. 271 (1982) (reviewing GUIDO CALABRESI, *A COMMON LAW FOR THE AGE OF STATUTES* (1982)).

206. See *supra* note 139; see also Redish, *supra* note 145, at 1443 (emphasizing the "principle of epistemological humility" and concluding that, "viewed from the broad perspective of history, any attempt by the government to lock in a prevailing scientific consensus is likely to be either futile or dangerous"); Tarsney, *supra* note 194, at 564-68 (explaining that constant technological and scientific advances make prophylactic restrictions on environmental marketing claims inappropriate).

B. Product Warning Statements

Although one might object to government-mandated warning statements as an example of coerced speech,²⁰⁷ the Supreme Court has endorsed risk labeling as one type of disclosure that may be required to combat otherwise misleading claims of product safety or effectiveness.²⁰⁸ The government still would have to demonstrate that a particular warning requirement is reasonably necessary to accomplish such a purpose. Warnings often are justified as necessary to provide complete information about a product, without which the labeling might be misleading for failing to include material information. Mandatory risk labeling which itself provides misleading or exaggerated information in pursuit of some other purpose, such as encouraging manufacturers to reformulate their products,²⁰⁹ seems constitutionally problematic. Nonetheless, because mandatory warnings are limited disclosure requirements rather than prophylactic prohibitions on truthful labeling, the government's power to demand warnings generally is accepted as legitimate. In fact, such labeling frequently is regarded as a favorable compromise for manufacturers in situations where the product itself otherwise might have been banned.

As explained previously, however, government risk labeling requirements often are accompanied by strict prohibitions on the voluntary provision of additional or clarifying information.²¹⁰ These restrictions are justified as necessary to protect the integrity of the risk information designed by lawmakers, so that manufacturers will not

207. See *McIntyre v. Ohio Elections Comm'n*, 115 S. Ct. 1511, 1519-22 (1995); *Riley*, 487 U.S. at 795-98; *Pacific Gas & Elec. Co. v. Public Utils. Comm'n*, 475 U.S. 1, 11-21 (1986) (plurality); *Wooley v. Maynard*, 430 U.S. 705, 714-15 (1977); *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241, 256 (1974). In defending its proposed requirement that the tobacco industry underwrite a \$150 million annual public education campaign to discourage smoking by youngsters, the FDA cited decisions upholding "corrective" advertising orders imposed by other agencies. See 60 Fed. Reg. 41,314, 41,356 (1995). It should be noted, however, that the courts have sometimes modified such orders when they seemed overly broad. See, e.g., *National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978).

208. See *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 n.24 (1976) (explaining that it may be appropriate to require that a commercial message "include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive"); cf. *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 34 (1990) (rejecting claim that risk disclosure regulation was subject to the Paperwork Reduction Act, noting that an "agency chooses to impose a warning requirement because it believes that such a requirement is the least intrusive measure that will sufficiently protect the public").

209. See Noah, *supra* note 40, at 313-14 (describing CPSC and FDA warning requirements for CFCs), 342-43 (describing California's carcinogen warning requirement).

210. See *supra* Part I.C.

dilute the impact of mandatory warning statements by including disclaimers.²¹¹ In some instances, such limitations have generated significant controversy. The FDA's formal prohibition on disclaimers to product warnings emerged during a long-running battle with a group of physicians who treated diabetic patients.²¹² On the basis of a government study which had been criticized for a variety of methodological flaws, the Agency decided to require a warning in the labeling of oral hypoglycemic agents,²¹³ and it successfully rejected the physicians' request that their disputes with the study's design be included anywhere in the warning.²¹⁴ But even if the Agency is confident that it has struck the appropriate balance at the time it first issues such a warning requirement, new information frequently comes to light justifying a revision in labeling that the FDA cannot respond to promptly because it must first initiate the frequently slow process of revising the regulation.

Even with products directed to lay consumers, some restrictions on the permissible content of warning labels make little sense. For instance, the so-called exclusivity rule for OTC drug products, which prohibits even the slightest deviation from the FDA's prescribed warning statements, does not seem to be justifiable as necessary to reduce potentially misleading claims in labeling. Strict warning requirements of this sort promote uniformity, but it remains unclear whether such uniformity actually advances any substantial public health interest or, instead, just simplifies the FDA's compliance monitoring activities. Only recently did the Agency permit companies to substitute certain synonyms within the mandatory warning statements.²¹⁵

211. See 40 Fed. Reg. 28,582, 28,583 (1975) ("[W]arnings about possible hazards associated with the use of a drug must, to be effective, remain undiluted by expressions of opinion discounting the risk."); 39 Fed. Reg. 33,229, 33,232 (1974) ("[W]here warnings are required, disclamatory opinions necessarily detract from the warning in such a manner as to be confusing and misleading."). Ironically, the FDA recently encouraged manufacturers of certain therapeutic products to include disclaimers with the EPA's mandatory warning for ozone depleting substances so as not to discourage medically necessary uses. See 58 Fed. Reg. 34,812, 34,813 (1993).

212. See Gina B. Kolata, *Controversy over Study of Diabetes Drug Continues for Nearly a Decade*, 203 SCIENCE 986 (1979). One of the skirmishes in this battle concerned the physicians' request under the Freedom of Information Act for access to the study's records, a request that the FDA successfully denied. See *Forsham v. Califano*, 587 F.2d 1128, 1133-34 (D.C. Cir. 1978), *aff'd*, 445 U.S. 169 (1980).

213. See 21 C.F.R. § 310.517 (1994).

214. See *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973).

215. See 59 Fed. Reg. 3998, 4000 (1994) (codified at 21 C.F.R. § 330.1(i) (1994)) (allowing OTC drug product manufacturers to interchange words such as "consult" and "ask," and "physician" and "doctor"). In other cases, the FDA has only provided detailed guidelines

Finally, limitations on the inclusion of additional risk information in labeling seem especially dubious. Like the rules against disclaimers, the FDA regards such a prohibition as necessary to preserve the integrity of the warning labels that it has so carefully designed. Nonetheless, unlike disclaimers which might be used in an effort to circumvent an agency's judgment that a product poses a significant risk, manufacturers may wish to provide additional warnings even though they may lose sales as a result.²¹⁶ To be sure, the government has an interest in preventing both the dilution of existing warnings by unnecessary label clutter and the possibility of overreaction to additional warnings of less serious or unsubstantiated risks.²¹⁷ A blanket prohibition on the inclusion of additional risk information does not, however, seem narrowly tailored to advance these goals.

C. Continuing Medical Education Programs

The FDA frequently defends strict labeling restrictions by noting that it does not limit the discussion of scientific information through other channels.²¹⁸ Although not a direct labeling restriction, the Agency's proposed limitations on CME programs represent yet another effort to restrict the transmittal of truthful, nonmisleading information in the pursuit of a secondary governmental goal. Whereas the FDA has enacted a blanket prohibition on all unapproved health claims in food labeling, the proposed regulation of industry-supported educational activities is somewhat more subtle, and potentially more pernicious.²¹⁹ The Agency

for the types of risk information that must appear in labeling. See 21 C.F.R. § 801.430(d) (1994) (requiring toxic shock syndrome warning for tampons).

216. The additional warnings nonetheless may be motivated by self-interest, as companies attempt to minimize their tort liability. The FDA sometimes objects to what it regards as "defensive" labeling that lacks any basis in experience with a product. See Noah, *supra* note 50, at 148-50 & n.52.

217. See Noah, *supra* note 40, at 381-90. A similar argument might be made in defense of strict food labeling controls. See 58 Fed. Reg. 2079, 2107 (1993) (noting that the inclusion of excessive information "would interfere with consumers' abilities to use the information of the greatest public health significance").

218. See, e.g., 59 Fed. Reg. 395, 422 (1994) ("Adequate alternative channels remain for the dissemination of scientific information. For example, regulation of the information that may appear on the food label in no way affects the ability of a scientist to publish experimental results in a journal."); 40 Fed. Reg. 28,582, 28,583 (1975); 39 Fed. Reg. 33,229, 33,231 (1974) ("[D]ebate and disagreement is properly the subject of scientific discussions in professional journals and symposia, but not in drug labeling.").

219. See Charles J. Walsh & Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325, 1363-69 (1994). While no final regulations have been issued to implement the provisions of the *Draft Policy Statement*, the very existence of the published

already prohibits any labeling references to unapproved therapeutic uses of approved drugs or medical devices.²²⁰ The CME policy attempts to prevent any direct or indirect manufacturer involvement in discussions of such off-label uses even when they occur in scientific rather than commercial settings, and even though the Agency repeatedly has recognized the lawfulness and even value of off-label prescribing by physicians.²²¹ With regard to CME activities, it is even more difficult to understand how a prohibition on company-supported educational activities relating to that company's own products can be justified in light of the First Amendment concerns discussed above.

As previously explained, the policy would regulate as promotional labeling or advertising all company-supported educational activities which relate to a company's product.²²² The proposal does not entirely prohibit industry financial support of continuing medical education; rather, it threatens supporting companies with enforcement action against their products if their support is perceived as tainting the information presented. Nonetheless, as the FDA candidly admits, "the constraints on advertising and labeling, when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views."²²³ Thus, the *Draft Policy Statement* might impermissibly chill the socially valuable exchange of scientific ideas. The asserted governmental goal is to ensure that companies within the industry do not use their support of CME programs as a guise for promoting their products, especially off-label uses of their products.²²⁴ The *Draft Policy Statement* draws a line between activities performed by, or on behalf of, a company and those which are essentially independent of company influence.²²⁵

"draft" is sufficient to curb industry-sponsored educational and scientific activities dramatically. See Arthur N. Levine, *FDA's Expanding Control Over Drug Promotion*, in *BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION* 23, 37-38 (Richard T. Kaplar ed., 1993). Despite the absence of final regulations, the matter has been deemed ripe for judicial review. See *Washington Legal Found. v. Kessler*, 880 F. Supp. 26, 33-36 (D.D.C. 1995).

220. See 21 U.S.C. §§ 355(d)(1), 360e(d)(2)(A) (1994); 21 C.F.R. §§ 201.56(c), 801.5(a) (1994); 40 Fed. Reg. 15,392, 15,394 (1975).

221. See Noah, *supra* note 50, at 142-44.

222. See *supra* Part I.D.

223. 57 Fed. Reg. at 56,412 (footnote omitted).

224. See *id.*

225. See *id.*

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or

The FDA's attempt to regulate industry-sponsored scientific and educational activities raises a number of questions concerning the First Amendment rights of companies to speak about their products as well as the rights of professionals to receive accurate scientific information. At the very least, the content of scientific and educational programs is entitled to commercial speech protection, and some commentators have argued that this type of information qualifies as "mixed" or even "pure" speech deserving full First Amendment protection.²²⁶ In order to justify its proposed CME restrictions, therefore, the government must at least demonstrate that it has a substantial interest in regulating the speech in question, that its restriction directly advances this interest, and that the restriction is narrowly tailored to accomplish its goal.²²⁷ Unlike its food labeling preambles, the Agency has offered no real constitutional defense of its CME policy.²²⁸

otherwise use the presentation as an advertising vehicle. FDA is concerned that companies may influence content of educational programs not only directly, by being involved in the selection of speakers or in the treatment of topics, but also indirectly through the nature of the relationship between the company and the provider (e.g., if the provider believes that future financial support from the company depends upon producing programs that promote the company's products).

Id. at 56,412-13.

226. See Redish, *supra* note 145, at 1443-44 ("Few free speech observers would find constitutionally tolerable a widespread system of governmental suppression of scientific opinion, even when that opinion differed dramatically from the prevailing scientific consensus The belief that the very same scientific claims automatically lose their full level of constitutional protection when made by a product manufacturer in a commercial advertisement needs some logical basis, in terms of free speech theory, for the drawing of such a strict dichotomy. It is doubtful, however, that such a basis may be found." (footnote omitted)); *cf.* *Rubin v. Coors Brewing Co.*, 115 S. Ct. 1585, 1594-95 (1995) (Stevens, J., concurring in judgment) (suggesting that the distinction between commercial speech and full First Amendment protection is inappropriate where the restriction in question "neither prevents misleading speech nor protects consumers from the dangers of incomplete information").

227. See *Coors*, 115 S. Ct. at 1590-93; *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 564-66 (1980).

228. In response to First Amendment criticisms leveled against the Agency for its broad regulation of communications concerning therapeutic products, one high-ranking FDA official merely offered a reiteration of the defenses presented in the preambles to the NLEA implementing regulations. See David G. Adams, *FDA Regulation of Communications on Pharmaceutical Products*, 24 SETON HALL L. REV. 1399, 1414-15 (1994) ("Although the agency has yet to address these questions in any formal manner with regard to pharmaceutical products, the agency has addressed similar issues in the context of food labeling. . . . [T]he agency stated that the restrictions on speech inherent in regulation of labeling claims are incidental and related to regulation of the products themselves and that, in any event, the constitutional protections for commercial speech are not abridged by the proposed regulation." (footnote omitted)).

The proposed restrictions have no direct, immediate connection to the FDA's asserted purpose of preventing the dissemination of false or misleading statements about drug products and medical devices. The proposal does not seek to regulate statements which are actually false or misleading, but rather statements which the Agency *presumes* may tend to be false or misleading. There is little basis to support the FDA's intuitive, *ex ante* judgment that the close involvement of a pharmaceutical or medical device company in a CME program necessarily taints the information presented. The fact that a speaker may be motivated by self-interest has long been deemed an insufficient basis for stripping speech of constitutional protection.²²⁹

Moreover, while the food labeling regulations were enacted under a mandate from Congress, and are supported by something of a legislative record, the proposed restrictions on scientific and educational activities do not rest on nearly so solid a foundation. The *Draft Policy Statement* contains little justification for the proposed restrictions beyond the assertion that company-sponsored events pertaining to company products are promotional and, therefore, are subject to Agency constraints on advertising and labeling.²³⁰ Concerns about the potential to mislead, which may be valid in the context of consumer product labeling, seem much less reasonable where the intended audience is a group of highly-educated and sophisticated professionals with specialized knowledge in the fields being discussed.²³¹ The proposed guidelines do not directly

229. See, e.g., *Board of Trustees of the State Univ. v. Fox*, 492 U.S. 469, 482 (1989) ("Some of our most valued forms of fully protected speech are uttered for a profit.").

230. In its most recent discussion of the matter, the FDA takes the following position:

Because drugs and devices are regulated based on their "intended use" . . . , the agency's policies may have an unavoidable effect on the dissemination of information regarding unapproved uses for approved products. However, FDA emphasizes that these policies are narrowly drawn and are intended to further describe FDA's regulation of drugs and devices (not speech), to ensure that sponsors demonstrate that their drugs or devices are safe and effective for their intended uses, and to protect consumers from the risks associated with the unapproved use of drugs and devices whose safety and efficacy for the unapproved use have not been established.

59 Fed. Reg. 59,820, 59,825 (1994). The Agency also noted that its "broad experience reviewing promotional materials and scientific data suggests that determining whether information is 'truthful' may depend on a variety of factors, including time, context, publication bias, [and] lack of stringent [peer] review." *Id.* at 59,826; see also 60 Fed. Reg. 62,471, 62,472 (1995) (inviting comments on draft FDA guidance which would allow companies to disseminate reprints of peer-reviewed scientific articles).

231. See Noah, *supra* note 40, at 326-27, 346 (describing the FDA's and courts' recognition of the special status of physicians); Paul H. Rubin, *Are Pharmaceutical Ads Deceptive?*, 49

advance the Agency's asserted interest in preventing false or misleading speech about the therapeutic products which it regulates.

Furthermore, the possibility that biased information might be presented at a company-sponsored educational event does not justify the wholesale burdening of this category of speech. On the contrary, the policing of industry-sponsored educational and scientific events seems ideally suited for case-by-case adjudication. It is generally inappropriate to restrict an entire category of speech in order to guard against a possible subset of false or misleading speech. The CME guidelines are not narrowly tailored to accomplish the government's objective. Because it would regulate as advertising all product-related speech funded or otherwise supported by a company, the policy clearly is more "expansive than necessary."²³²

IV. CONCLUSION

It remains unclear, in light of recent developments in commercial speech case law, how the courts will react to government initiatives such as the FDA's food labeling regulations and CME policy. It is very likely, however, that these broad regulatory schemes will be challenged by affected parties. Recent decisions suggest that commercial speech, so long as it is truthful and nonmisleading, will continue to receive heightened protection.²³³

FOOD & DRUG L.J. 7, 18-19 (1994); see also *The Florida Bar v. Went For It, Inc.*, 115 S. Ct. 2371, 2382 (1995) (Kennedy, J., dissenting) ("Speech has the capacity to convey complex substance, yielding various insights and interpretations depending upon the identity of the listener or the reader and the context of its transmission.").

232. *Board of Trustees*, 492 U.S. at 476-77; *Central Hudson*, 447 U.S. at 565 ("The regulatory technique may extend only as far as the interest it serves.").

233. As this Article went to publication, the Supreme Court decided *44 Liquormart, Inc. v. Rhode Island*, striking down the State's prohibition against alcohol price advertising. See 64 U.S.L.W. 4313, 4322 (May 13, 1996); see also *supra* note 129 (discussing the lower court decisions in the case). The Court held unanimously that the Twenty-First Amendment provided the State with no presumption of constitutional validity, but the Justices disagreed substantially over the proper First Amendment rationale for the Court's decision. In his plurality opinion, Justice Stevens argued that the advertising prohibition failed *Central Hudson's* nexus prongs, dismissing the holding in *Posadas* as an aberration and suggesting that outright bans on commercial speech should be subject to closer constitutional scrutiny. See 64 U.S.L.W. at 4319-22. Justice O'Connor, in an opinion joined by Chief Justice Rehnquist and Justices Souter and Breyer, concurred in the judgment on the narrower ground that the challenged restriction failed *Central Hudson's* fourth prong. See *id.* at 4326-27 (refusing to adopt a new analysis for evaluating commercial speech). In his separate concurrence, Justice Thomas concluded that the government's asserted interest (i.e., keeping consumers of lawful products ignorant of truthful information to manipulate their marketplace choices) was illegitimate *per se*. See *id.* at 4323.

The shift to rulemaking and away from the classic adjudicatory model of enforcement actions against false or misleading claims poses important constitutional questions. As recently elaborated in *Rubin v. Coors*, commercial free speech doctrine may disempower agencies from engaging in otherwise authorized rulemaking, such as the regulation of labeling and advertising, where the effect of such regulation is over- or underinclusive. Rulemaking to limit truthful statements merely on the basis that they may have some potential to mislead is sloppy lawmaking, paternalistic, and constitutionally unsound.